UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TRUTEK CORP. ***Plaintiff,*** **v.** **Yeong Wan Cho (a.k.a Peter Cho); Abdul Gaffar; Sei Young Yun; Salvacion USA, Inc.; Salvacion International, LLC; Salvacion Co., Ltd.; Salvacion R&D Center; Biosure Global, Ltd.; Immobiliaria La Salvacion, R.D., John and Jane Does 1 through 10 (gender neutral fictitious names); ABC Corporation 1 through 10 (fictitious names),** ***Defendants.***	Case No. 2:23-cv-3709 **COMPLAINT** **JURY TRIAL DEMANDED**

PARTIES

1. Plaintiff, TRUTEK CORP. ("Trutek") is a corporation of the State of New Jersey, with principal offices at 281 East Main Street, Somerville, New Jersey, 08876.

2. According to information and belief, Defendant Yeong Wan Cho, *a.k.a.* Peter Cho (hereinafter, "Peter Cho" or "Cho") is an individual residing at 534A Hillside Avenue, Palisades Park, New Jersey 07652. According to

information and belief, Defendant Cho is a co-founder and principal of Salvacion USA, Inc.

3. According to information and belief, Defendant Abdul Gaffar (hereinafter, "Gaffar") is an individual residing at 8351 Catamaran Circle, Lakewood Ranch, Florida 34202. According to information and belief, Defendant Gaffar is a co-founder and principal of Salvacion USA, Inc.

4. According to information and belief, Defendant Sei Young Yun (hereinafter, "Yun") is an individual residing at 204-1106 ho, 127 Dunsannam-ro, Sri-gu, Daejeon 35249, Korea. According to information and belief, Defendant Yun is a co-founder and principal of Salvacion USA, Inc.

5. According to information and belief, Defendant Salvacion USA, Inc. ("Salvacion USA") is a corporation organized and existing under the laws of the State of New Jersey, doing business at 210 Sylvan Avenue, #24, Englewood Cliffs, New Jersey 07632.

6. According to information and belief, Defendant Salvacion International LLC (hereinafter, "Salvacion International") is a limited liability company organized under the laws of the State of Wyoming, doing business at 1309 Coffeen Avenue, Suite 1200, Sheridan, Wyoming 82801.

7. According to information and belief, Defendant Salvacion Co., Ltd. is a corporation organized under the laws of the country of Korea, doing

business at 557 GangNam-daero (SungHan B/D), 12th Floor, SeoCho-gu, Seoul, Korea 06531.

8. According to information and belief, Defendant Salvacion R&D Center is a business organized under the laws of the country of Korea, doing business at Migun-Technoworld B/D, YuSeong-guDaejeon, 34025 Korea.

9. According to information and belief, Defendant Biosure Global, Ltd. (hereinafter, "Biosure Global") is a corporation organized under the laws of the United Kingdom, Registered Company No. 11230071, doing business at 121 Brooker Road, Waltham Abbey 3N9 1JH UK, United Kingdom and at Hillgrove Essex Park, Nazeing, Essex, UKEN9 2HB, United Kingdom.

10. According to information and belief, Defendant Inmobiliaria La Salvacion, R.D. is a business organized under the laws of the Dominican Republic, doing business at Ave. Imbert Esq. C/Santiago Rodriguez, Pontezuela Santiago, Republica Dominicana.

FEDERAL SUBJECT MATTER JURISDICTION

11. The subject matter jurisdiction of this Court arises under 28 U.S.C. § 1331 concerning a federal question, the Patent Laws of the United States, 28 U.S.C. §§ 1338(a), (b), and 35 U.S.C. § 271, Theft of Trace Secrets Act, 18 U.S.C. § 1832, and the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. §§ 1961-1968.

SUPPLEMENTAL SUBJECT MATTER JURISDICTION

12. This court may exercise supplemental jurisdiction over the following counts for one or more of the defendants in this matter:

- breach of contract;
- breach of the implied covenant of good faith and fair dealing;
- theft of trade secrets (New Jersey state claim);
- concealment;
- unjust enrichment;
- conversion;
- interference with prospective economic advantage;
- unfair business practices; and
- civil conspiracy.

IN PERSONAM JURISDICTION

13. *In personam* jurisdiction over the individual Defendant Cho is proper because he resides in the State of New Jersey.

14. *In personam* jurisdiction over the individual Defendant Gaffar is proper because he has sufficient minimum contacts with the State of New Jersey by virtue of his involvement with the business entity of Salvacion USA.

15. *In personam* jurisdiction over the individual Defendant Yun is proper because he is a citizen and resident of Korea, and he has sufficient minimum contacts with the State of New Jersey by virtue of his involvement with the business entity of Salvacion USA.

16. *In personam* jurisdiction over Salvacion USA is proper because the business entity is a citizen of the State of New Jersey by virtue of its incorporation therein.

17. *In personam* jurisdiction over Defendant Salvacion International is proper under 28 U.S.C. § 1400(b) because the tort of patent infringement occurred in New Jersey and Salvacion International is an integral part of an enterprise that has an established place of business in New Jersey.

18. *In personam* jurisdiction over Defendants Salvacion Co., Ltd., Salvacion R&D Center, Biosure Global, and Inmobiliaria La Salvacion, R.D. is proper because they are citizens of and reside in foreign countries.

VENUE

19. The venue of this Court is proper under the Patent Venue Statute, 28 U.S.C. § 1400(b) since the tort of patent infringement occurred within the State of New Jersey, and Defendant Salvacion International is an integral part of an enterprise that has an established place of business thereat, and which is furthermore located within the venue of the District of New Jersey.

20. The venue of this Court is proper because Defendant Cho is a resident of the State of New Jersey.

21. The venue of this Court is proper because Salvacion USA is a citizen and resident of New Jersey by virtue of incorporation therein and having an established place of business in New Jersey.

22. The venue of this Court is proper because individual Defendants Gaffar and Yun each have sufficient minimum contacts with the State of New Jersey.

23. The venue of this Court is proper because Defendants Salvacion Co., Ltd., Salvacion R&D Center, Biosure Global, Ltd., and Inmobiliaria La Salvacion, R.D. are citizens of and reside in foreign countries and they each an integral part of an enterprise that committed torts against Plaintiff, a New Jersey corporation.

STATEMENT OF FACTS AND CAUSES OF ACTION

The Business of Plaintiff, Trutek Corp

24. Plaintiff, Trutek Corp. ("Trutek") is a New Jersey corporation having offices in Somerville, New Jersey. Trutek develops and markets over-the-counter products that utilize electrostatic fields to relieve symptoms due to nasally inhaled airborne particles, pollutants, and allergens and to inhibit infection from harmful particles (*e.g.,* bacteria, viruses, fungi). The products are sold in the form of gels and liquids. Most of these products are applied directly to the user's nostrils. However, Trutek also markets liquids that are sprayed into the nostrils or onto a porous face mask to enhance its protection.

Trutek's products are marketed and sold worldwide. In the United States, most of these products are marketed under the brand name NasalGuard®.

25. Trutek has an intellectual property portfolio comprising several patents, trademarks, and trade secrets. Trutek's intellectual property also comprises goodwill, trade names, manufacturing and selling processes, knowhow and techniques, secret formulae, copyrights, designs, and other materials employed in connection with the manufacture, assembly, packaging, offering for sale, advertisement, promotion and sale of its products.

26. Among its United States patents are US 5,674,481 B2, US 6,844,005 B2, US 8,163,802 B2, US 9,737,497 B2, and US 9,750,706 B2. Other patents are pending. Trutek has always caused its existing patent numbers to marked on the packaging of all of its products as required by 35 U.S.C. § 287.

27. Trutek's United States trademarks include word marks of TRUTEK®, NasalGuard®, NasalGuard Allergie Block®, and NasalGuard Airborne Particle Blocker®.

Defendant Peter Cho's Relationship With Trutek

28. On or about March 1, 2019, Ashok Wahi ("Wahi"), then President of Trutek, was introduced to Defendant Peter Cho ("Cho"). Cho is the President of Jintec America, Inc. ("Jintec"), a New Jersey Corporation. Jintec is a United States affiliate of a South Korean holding company (Jintec Holdings). Wahi

and Cho were introduced by an executive officer of one of Trutek's contract manufacturers. Cho indicated to Wahi that Jintec was interested in becoming an exclusive distributor for Trutek's NasalGuard Airborne Particle Blocker® gel in South Korea.

29. On March 4, 2019, Cho and Wahi entered into a Confidential Disclosure Agreement ("CDA") in which Trutek agreed to disclose to Cho confidential information regarding:

> *NasalGuard® with special features, attributes and additional claims, Miracle Under-Eye™, NasalGuard® Unscented, NasalGuard Allergie Block®, NasalGuard Cold & Flu Block ™, NasalGuard® Multi-Acting ™, NasalGuard® Single Application Sachets, NasalGuard MF, NasalGuard Airborne Particle Blocker, NasalGuard Personal Air Filter Gel, NasalGuard Particle Blocking Gel, Anti-Stat Enhanced Mask™, NasalGuard Wipes ™, NasalGuard Allergie Wipes ™, NasalGuard Cold & Flu Wipes ™, Skin and Hair super conditioners, Truteks® Skin and Truteks® skin care products, nasal application (anti-stat) diagnostic products and, associated Technologies and Methodologies, Patented and Pending, Patent Applications, Chloraseptic Allergie Block and Little Allergies, Allergie Block, Eisai Crystal Veil, Eisai Crystal Veil cool, Nitto Nuru Mask, Nitto NasalGuard, including but not limited to nasal application product lines such as gels, pre-moistened products for e.g. applicators, swabs, wipes, etc., sticks, nasal sprays, nasal washes, surgical masks, multi-acting/integrated products, etc., and all other Trutek products.*

30. In return, Cho agreed *inter alia* to maintain the information in strict confidence and not to profit from the information except by written agreement from Trutek. Moreover, he agreed that "all inventions and improvements, patentable or not" that were associated with the disclosure would belong to Trutek. A copy of the executed CDA dated March 4, 2019 is attached hereto as Exhibit 1.

31. Discussions between Wahi and Cho continued for another two months during which Cho reviewed Trutek's patented and trade secret technology, manufacturing methodologies, and intellectual property. On May 12, 2019, Trutek and Jintec entered into an agreement ("the May 12th Agreement") for "Importation, Marketing, Sales, and Distribution of Trutek's NasalGuard® Gel-Tube Product in South Korea." Jintec was to be the exclusive distributor for Trutek's products in South Korea. In exchange, Jintec was to purchase certain annual minimum quantities of the NasalGuard® gel tubes. A copy of the executed May 12th Agreement is attached hereto as Exhibit 2.

32. Clause II(a) of the May 12th Agreement (Page 1) also provides:

> *Trutek does not grant and Jintec does not claim and will not claim any rights whatsoever with respect to Trutek's Trade Secrets and Intellectual Property (hereafter "IP"), and Jintec hereby acknowledges Trutek's exclusive right and title in the Territory and elsewhere to the Products and Trutek's Trade Secrets and Intellectual Property. The phrase "Trutek's Trade Secrets and Intellectual Property" refers to Trutek's trademarks, patents and patents-pending, goodwill, trade names, trade secrets, manufacturing and selling processes, knowhow and techniques, secret formulae, copyrights, designs, and other materials of any kind whatsoever employed in connection with the manufacture, assembly, packaging, offering for sale, advertisement, promotion and sale of the Products. In addition, Jintec shall not attempt to manufacture or commission the manufacturing of the Trutek's product NasalGuard herein or any products, which shall be developed by Trutek in the future.*

33. Cho and Wahi executed the May 12th Agreement on behalf of Jintec and Trutek, respectively. The March 4th CDA between Wahi and Cho was duplicated on Page 9 of the Agreement, and it was made an integral part thereof.

34. On November 6, 2019, Trutek and Jintec entered into a second agreement ("the November 6th Agreement") for "Importation, Marketing, Sales, and Distribution of Trutek's NasalGuard® Gel-Tube Product in Greater China and Vietnam." Jintec was to be the exclusive distributor for Trutek's products in China and Vietnam. A copy of the executed November 6th Agreement is attached hereto as Exhibit 3. The November 6th Agreement contained the same Clause II(a) on Page 1, duplicated from the May 12th Agreement, *supra* and included therein. Once again, the CDA was integrated into the November 6th Agreement.

35. The relationship between the parties started off well. Jintec ordered products from Trutek, and the products were delivered to Jintec. At some point, a dispute arose between the parties where Jintec stopped paying Trutek for delivered product and failed to order minimum quantities of product. On March 26, 2021, Trutek filed suit against Jintec in the Superior Court of New Jersey in Somerset County (Docket No. SOM-L-426-21). The Trutek v. Jintec lawsuit is unrelated to the Present Above Captioned Complaint. However, the agreements have a binding effect on the Defendants in the Present Matter.

Trutek's Airborne Particle Blocking Technology and the '802 Patent

36. One of Trutek's best selling products is the NasalGuard® Airborne Particle Blocker ("APB product"). The most likely type of respiratory infection occurs when a person inhales germs through his nose into his lungs and bronchial tubes. The APB product comes in the form of a gel in a tube that a person applies to his nostrils. The gel is applied as a thin film. Most germs (*e.g.,* bacteria, viruses, fungi, *etc.*) have a negative electrostatic charge. Trutek's APB product sets up a positive electrostatic field around the user's nose. Airborne germs that float around the user's nose are attracted to the gel. The gel is sticky, and the germs are held in place by the sticky gel. One of the ingredients of the gel is a biocide that kills living organisms. Thus the germs that stick to the gel are killed. So, if some germs are dislodged from the gel and are inhaled, those germs are probably dead and harmless.

37. Although the APB gel is the most popular item, Trutek also markets nasal sprays, and liquids using the same technology. Trutek also sells a liquid spray product for face masks. Spraying this product onto a porous face mask renders the mask much safer to use because germs will be trapped in the mask even before they reach the user's nose. Using the gel together with a sprayed mask should greatly reduce the probability of infection due to nasal inhalation.

38. Trutek's U.S. Patent 8,163,802 ("the '802 Patent") is one of several patents that disclose and claim the fundamental operations and formulations that define the APB product. The '802 Patent is attached hereto as Exhibit 4. Claim 1 is an independent method claim, and claim 2 is an independent formulation claim. The formulation contains a cationic agent (*i.e.,* a substance that has a positive electrostatic charge). It also contains a biocide. A formulator adjusts the ingredients so as to make the formulation into a thin film that adheres to the skin or tissue. He or she also adjusts the formulation to be viscous and to hold the harmful germs in place so that the biocide can kill them and so that they would not dislodge.

39. The May 12th and November 6th Agreements between Trutek and Jintec covered importation, marketing, sales, and distribution of the APB product in South Korea and China/Vietnam, respectively. Trutek's NasalGuard® technology was fully disclosed to Cho. He understood the formulations and their ingredients. This is evidenced by his insistence that the formulation in the May 12th Agreement be modified to substitute specific ingredients therein for approval by the South Korean government. South Korea would not permit the product to be imported unless the product was thus modified. Cho was also aware of the '802 Patent.

Defendants Peter Cho and Salvacion USA, Inc.

40. Sometime around January 24, 2023, people at Trutek discovered Cho's involvement with Defendant, Salvacion USA, Inc. ("Salvacion USA") According to information and belief, Defendant Cho and Defendant Dr. Abdul Gaffar ("Gaffar") are co-founders of Salvacion USA. However, it is currently unknown what position each holds in the company.

41. Salvacion USA is a New Jersey Corporation - Company No. 0450535127 - incorporation date August 27, 2020. ***The business address of Salvacion USA is the same as that for Jintec.*** According to information and belief, Salvacion USA is a company member of a global business Enterprise ("the Salvacion Enterprise"), comprising additionally of Defendants: (1) Cho, (2) Gaffar, (3) Yun, (4) Salvacion Co. Ltd. (a South Korean company), (5) Salvacion R&D Center (a South Korean company), (6) Salvacion International, LLC (a Wyoming corporation), (7) BioSure Global (a UK company), and (8) Salvacion R.D. (a Dominican Republic company).

Salvacion USA and COVIXYL Over-the-Counter Products

42. Salvacion USA is listed as a manufacturer of drugs and pharmaceuticals with an NDC labeler name of Salvacion USA, Inc. According to information and belief, Salvacion USA created and sold an over-the-counter product called Covixyl-G Nasal Antiseptic Solution (NDC No. 808570-100). Salvacion USA filed for FDA approval in November 2020 as an OTC

product. The main ingredient in the Covixyl-G formulation is benzalkonium chloride in a 0.13% solution. The label claims that the formulation uses a "nanotechnology" delivery system. A typical nanotechnology delivery system consists of an oil-in-water nanoemulsion (a.k.a. microemulsion) consisting of micron-sized nano-droplets also containing the benzalkonium chloride. A copy of the packaging for the Covixyl-G product is shown in Exhibit 5, attached hereto. According to information and belief, the manufacture or sale of Covixyl-G by the Salvacion Enterprise infringes on the claims of the '802 Patent.

43. It should be noted that claims 6 and 7 of Trutek's '802 Patent state that the cationic and biocidic agents in its formulations are benzalkonium chloride. Application of a 0.13% solution of benzalkonium chloride to a person's nostrils would create a positively charged electrostatic field of sufficient strength to attract the negatively charged germs. The microemulsion droplets would surround the germs and hold them in place, while the benzalkonium chloride would deactivate them via membrane disruption.

44. On January 14, 2022, Salvacion USA filed a U.S. non-provisional patent application claiming priority to a PCT[1] international patent application (filed October 15, 2020), and then to a provisional patent application (filed August

[1] PCT is an acronym for Patent Cooperation Treaty.

31, 2020). The current status of the application is patent pending. The title of the patent application is, "Antiviral Composition and Use For the Same." The inventors listed on the application are Gaffar, Cho, and Yun. The application was published on May 5, 2022 by the USPTO as Application Publication Serial No. US 2022/0133783 A1 ("the '783 Application"), a copy of which is attached hereto as Exhibit 6. The '783 Application discloses and claims an anti-viral formulation "containing a cationic anti-viral agent (cationic surfactant) and a copper salt to control viral infections in the nasopharyngeal and throat area of humans and animals." The '783 Application's specification discloses several example formulations. "Solution 1" lists the ingredients of a formulation where the principal ingredient is *Ethyl Lauroyl Arginate Hydrochloride* ("ELAH"). "Solution 2" lists the ingredients of a formulation where the principal ingredient is benzalkonium chloride. It also lists a formulation of a nasal gel, where the principal ingredient is either ELAH or benzalkonium chloride. According to the patent application's disclosure and claims, the delivery system for the ingredients is a microemulsion. As discussed earlier, a microemulsion comprises small micron sized individual droplets.

45. According to information and belief, sometime around July 27, 2021, Salvacion USA submitted an application to the FDA for its Covixyl-V

product for pre-emergency use authorization. In August 2021, Defendants Cho and Gaffar gave interviews to the media explaining that their new Covixyl product can be used regularly to protect against infection from Covid-19. Shortly thereafter, the product launched and was being sold online on *amazon.com*, and Target. It was no longer called Covixyl-V, but rather it was branded as Covixyl™. The text on the front of the packaging reads, "Helps Block Airborne Viruses." Photographs of the Covixyl product and the product packaging are attached hereto as Exhibit 7.

Salvacion Enterprise Activities With Covixyl

46. From Exhibit 7, note that the product package states, "Formulation protected by US Patent # 17/576,098. Made in the USA for Salvacion Int'l LLC Sheridan, WY 82801." According to information and belief, when the Covixyl product is ordered from *amazon.com*, the order is fulfilled by Salvacion International LLC ("Salvacion Int'l"), a Wyoming limited liability company.

47. According to information and belief, Defendant's Cho, Gaffar, Yun, and Salvacion USA are engaged in efforts to market Covixyl in South Korea. Exhibit 8 is a copy of a test report regarding samples of Covixyl-V submitted to the Korea Testing & Research Institute ("KTR") dated

2021.03.09. It should be noted that the address of Salvacion USA is the same as for Jintec.

48. In addition, Salvacion Enterprise member, Biosure Global (a United Kingdom company) sells a nasal spray product labeled BioSURE® PRO. A copy of a page from Biosure Global's website (*www.biosure.co.uk*) is attached hereto as Exhibit 9. When a user clicks on the link, "How does BioSURE® Pro Protective Nasal Spray work?" the following text appears:

> *BioSure PRO Protective Nasal Spray is a microemulsion formula, that is applied as a plume of droplets rather than a squirt, so it creates a temporary physical barrier in your nasal passages that blocks the virus spike proteins from entering the cells ACE-2 receptors in your nose. This helps block the first step of infection at the main entry point and it also helps prevent the virus from multiplying that physically blocks airborne viruses from attaching to the cells in your nose.*
>
> *The key ingredient is ELAH (Ethyl Lauroyl Arginine Hydrochloride), that has been safely and effectively used in a globally recognized mouthwash to block the growth of bacteria in the mouth.*
>
> *Clinical evaluations in humans and the lab have proven the effectiveness of ELAH at blocking airborne viruses, including RSV (common cold), influenza (flu), and COVID-19 delta and omicron variants.*

49. Considering the above text from Biosure's website, it is obvious that the product BioSURE® PRO formulation is virtually the same as that of Covixyl.

Infringement of the '802 Patent by the Salvacion Enterprise

50. On March 7, 2023, Mr. Nitin Kumar, a New Jersey resident, ordered two units of the Covixyl product from *amazon.com*. The order was fulfilled, and the products were received by him at his New Jersey address. Mr. Kumar

gave the products to Trutek in their original packages. Mr. Kumar's declaration is attached hereto as Exhibit 10.

51. Trutek personnel tested the Covixyl product in its own laboratories and determined that the product exhibits a surface electrostatic charge that is approximately equal to that of its own NasalGuard® product. It was confirmed that the product forms a thin film that adheres to surfaces such as skin or tissue, and it is sufficiently viscous to remain active in the user's nostrils for several hours. Based upon this verification that the product will electrostatically attract germs (harmful particles) and on online information provided by Salvacion itself, it is apparent that the Covixyl products infringe on at least Claims 1 and 2 of the '802 Patent. (See Exhibit 4.)

52. In March of 2023, two additional orders for the Covixyl product were placed by Keith Altman. The two additional units were delivered to his address in Michigan. Mr. Altman's declaration is attached hereto as Exhibit 11.

Offenses against Trutek by Defendant, Peter Cho

53. On March 4, 2019, Cho and Wahi entered into a binding agreement (the CDA) whereby Wahi would disclose Trutek's confidential information to Cho, and in return, Cho would not disclose said confidential information to any third party nor would Cho use it for any purpose unless authorized to do so in writing by Wahi. Cho further agreed that Trutek will have "sole and

irrevocable rights to all such improvements, inventions and Patents without any further verbal or written authorization from" Trutek.

54. Wahi disclosed its confidential and proprietary information and technology to Cho. Cho breached its contract with Wahi (the CDA) by disclosing this confidential information to others, and by using it for his own purposes without prior authorization from Wahi.

55. Cho became involved as a principal of a company that produces a competitive product based on Trutek's technology.

56. Cho failed to honor his contractual obligation by allowing a patent application for Trutek's technology to be assigned to Salvacion USA instead of to Trutek.

57. Cho knowingly and intentionally converted Trutek's proprietary technology for his own purposes and stole Trutek's trade secrets for his own purposes.

58. Cho knowingly conspired with other individuals and companies within the Salvacion Enterprise to utilize Trutek's proprietary technology for their own profit.

59. Cho knowingly and willfully induced those within the Salvacion Enterprise to infringe upon the claims of Trutek's '802 Patent.

Offenses against Trutek by Defendants Gaffar and Yun

60. Gaffar and Yun knowingly conspired with Cho to utilize Trutek's proprietary confidential information to make, use, and sell a product in the United States and worldwide that infringes on Trutek's '802 Patent in violation of 35 U.S.C. § 271(a).

61. Gaffar and Yun were complicit with Cho in developing the Covixyl product and in filing patent applications for the same. The product and the patent applications represent improvements over Trutek's proprietary confidential information, and they rightfully belong to Trutek.

62. Gaffar knowingly conspired with other individuals and companies within the Salvacion Enterprise to utilize Trutek's proprietary technology for their own profit.

63. Gaffar knowingly and willfully induced those within the Salvacion Enterprise to infringe upon the claims of Trutek's '802 Patent.

Offenses against Trutek by Salvacion USA

64. Salvacion USA infringes the claims of the '802 Patent by making, using, and selling an infringing product Covixyl in violation of 35 U.S.C. § 271(a).

65. Infringement of the '802 Patent by Salvacion USA is willful because at least one of its principals was aware of the '802 Patent and its technology before said infringement occurred.

66. Salvacion USA knowingly induced others to infringe on the claims of the '802 Patent.

67. Salvacion USA knowingly conspired with other entities within the Salvacion Enterprise to profit from technology that rightfully belongs to Trutek and not to Salvacion USA.

68. Salvacion USA intentionally and fraudulently claimed publicly that it had the right to market Covixyl products.

Offenses against Trutek by Salvacion International, LLC

69. Salvacion International infringes the claims of the '802 Patent by making, using, and selling an infringing product Covixyl in violation of 35 U.S.C. § 271(a).

70. Infringement of the '802 Patent by Salvacion International is willful because at least one of its principals was aware of the '802 Patent and its technology before said infringement occurred.

71. Salvacion International knowingly conspired with other entities within the Salvacion Enterprise to profit from technology that rightfully belongs to Trutek and not to Salvacion International.

Offenses against Trutek by Biosure Global

72. Biosure Global International intentionally conspired with other entities within the Salvacion Enterprise to profit from technology that rightfully belongs to Trutek and not to Biosure Global.

Offenses against Trutek by the Salvacion Enterprise and its members

73. Each member of the Salvacion Enterprise conspired with all other members to deprive Trutek of its technology. The members of the Salvacion Enterprise intentionally, knowingly, and fraudulently advertised electronically online offering to sell a product that it did not own and that belongs to Trutek. When they did sell their product rightfully belonging to Trutek, they accepted payment for their fraudulent activities electronically.

Offenses against Trutek as to the Actions of All Defendants

74. In the CDA, in exchange for Trutek disclosing proprietary and confidential information to Cho, Defendant Cho promised not to disclose said information to others. He further promised that any developments and improvements to said information would be assigned to Trutek.

75. Trutek disclosed said proprietary and confidential information to Cho, said confidential information including trade secrets belonging to Trutek. Further, Cho was aware of Trutek's '802 Patent.

76. Less than one year following disclosure of said confidential information to him, in a scheme to defraud Trutek of its intellectual property, Cho disclosed said information to Defendants Gaffar and Yun, who were acting in behalf of Defendant Salvacion USA.

77. Based on their receipt of said confidential information, and in a scheme to defraud Trutek of its intellectual property, Defendants Cho, Gaffar, and Yun filed three patent applications at the USPTO (a U.S. government agency) in behalf of Salvacion USA, which served as the applicant. The patent applications covered presumably patentable improvements over the inventions disclosed and claimed in the '802 Patent, and they utilized trade secrets belonging to Trutek. Although obligated to assign said patent applications to Trutek, Defendants Cho, Gaffar, and Yun assigned said patent applications to Salvacion USA.

78. The action of Defendants Cho, Gaffar, Yun, and Salvacion USA represented a scheme to defraud Trutek out of its rightfully owned intellectual property. Further, it was reasonably foreseeable that the patent applications would be filed using wire communications, and wire communications were in fact used to file said applications.

79. Although being aware of the '802 Patent, Defendants Cho, Gaffar, Yun, and Salvacion USA, failed to inform the USPTO of the existence and materiality

of said '802 Patent related to Defendants' patent applications in violation of 37 CFR § 1.56. Intentionally and knowingly failing to meet this requirement represents fraud on the Patent Office. Filing said patent application at the USPTO using wire communications while failing to inform the USPTO of its obligations to assign and of the existence and materiality of the '802 Patent, Defendants Cho, Gaffar, Yun, and Salvacion USA conspired to defraud Trutek by assigning Trutek's rightfully owned intellectual property to Salvacion USA.

80. Although being aware of the '802 Patent as well as their obligation to assign any improvements to said patent to Trutek, and in a scheme to defraud Trutek of profits derived from sales of its rightfully owned product, Defendants developed Covixyl-G, a product that infringes on the '802 Patent, and they applied for FDA approval of said product.

81. Although being aware of the '802 Patent as well as their obligation to assign any improvements to said patent to Trutek, and in a scheme to defraud Trutek of profits derived from sales of its rightfully owned product, Defendants developed, manufactured, and sold Covixyl-V (renamed to Covixyl™), a product that infringes on the '802 Patent.

82. Although being aware of the '802 Patent and the fact that Covixyl infringes thereon, and in a scheme to defraud Trutek of profits derived from sales of

its rightfully owned product, Defendants Salvacion USA and Salvacion International knowingly and intentionally sold said Covixyl™ product to customers throughout the United States, thus depriving Trutek of profits and making all customers potentially liable for patent infringement in violation of 35 U.S.C. § 271.

83. In an effort to defraud Trutek out of profits from improvements to its intellectual property, all Defendants formed a global enterprise, having headquarters in Korea, with member participants in the United States (*i.e.,* Cho, Gaffar, Yun, Salvacion USA, and Salvacion International), United Kingdom (*i.e.* Biosure Global), Korea (*i.e.,* Salvacion Co., Ltd, and Salvacion R&D Center), and the Dominican Republic (Immobilaria La Salvacion) to sell the Covixyl™ product globally, thus depriving Trutek of profits that would have been made were said Covixyl™ product not sold by the global enterprise.

84. Orders for sale of Covixyl™ products to customers were placed using interstate or foreign wire communications (Internet sales), and virtually all payments to the global enterprise from sales were made using wire communications. Product deliveries were made by mail.

GENERAL ALLEGATIONS

85. Plaintiff restates every fact and allegation set forth in all preceding paragraphs of this Complaint as if fully set forth herein.

86. Plaintiff owns intellectual property related to certain formulations based upon attracting and/or repelling electrostatically charged particles in and around a person's nasal passages by application of a product that maintains an electrostatic charge on the skin or mucous membranes. Plaintiff has expended considerable resources to inventing, formulating, and developing its inventions and products and to protecting its rights therein. Much of Plaintiff's technology is subject to trade secret protection. Plaintiff has a number of issued patents on its technology. One such patent is the '802 Patent. Plaintiff holds all rights, title, and interest to its '802 Patents. The '802 Patent is in full force and effect. Trutek is the legal owner of the '802 Patent and possesses all rights of recovery under the patent.

COUNT ONE — INFRINGEMENT OF THE ‘802 PATENT
(As to Salvacion USA and Salvacion International

87. Plaintiff restates every fact and allegation set forth in all preceding paragraphs of this Complaint as if fully set forth herein.

88. Plaintiff owns intellectual property relating to an electrostatically charged multi-acting nasal application product and method covered by the ‘802 patent. Plaintiff has expended considerable resources in inventing and

developing his inventions and protecting its rights therein. Plaintiff holds all rights, title, and interest in and to the '802 Patent by virtue of assignment. The '802 Patent was issued on April 24, 2012, and is in full force and effect. Plaintiff is the legal owner of the '802 Patent, and possesses all rights of recovery under the patent.

89. Defendants, Salvacion USA and Salvacion International, make, use, offer to sell, and sell at least one infringing product, *viz.*, Covixyl Nasal Spray, (the "Accused Product") which infringes on the ‘802 Patent, without authority or license from Plaintiff.

90. Defendants, Salvacion USA and Salvacion International, directly infringe upon at least claims 1 and 2 of the ‘802 Patent because the Accused Product forms a thin film when applied to a person's nasal passages, possesses an electrostatic charge by virtue of a cationic agent ingredient, and renders airborne particles harmless by virtue of a biocidic agent ingredient.

91. Defendants, Salvacion USA and Salvacion International, were aware of the existence of the '802 Patent prior to their making, using, offering to sell, and selling the Accused Product. Thus, Defendants' actions constitute willful infringement of the '802 Patent.

92. Defendants, Salvacion USA and Salvacion International, knowingly induced infringement and are continuing to knowingly induce infringement of the

'802 Patent by specifically encouraging and inducing others to use the patented invention within the United States.

93. Upon information and belief, Defendants, Salvacion USA and Salvacion International, exported the Accused Product that was made in the United States.

94. Plaintiff has been damaged as a result of Defendants' infringement of the '802 Patent and will continue to be damaged unless such infringement is enjoined by this Court pursuant to 35 U.S.C. §283.

95. Pursuant to 35 U.S.C. §284, Plaintiff is entitled to damages adequate to compensate in an amount not less than a fair and reasonable royalty.

96. Defendants' Accused Product is sold in the same commercial outlets as Plaintiff's products. Defendants' product competes directly with Plaintiff's products. Every product sold by Defendants is a product that could have been sold by Plaintiff. Thus, Plaintiff should be entitled to its lost profits from sales it was unable to make.

97. Plaintiff is entitled to enhanced damages and attorney fees because infringement of the '802 Patent by Defendants was willful.

98. Alternatively, Plaintiff is entitled to a judgment from the Court, which enjoins sales or commercialization by Defendants of its product until after expiration of the '802 Patent.

WHEREFORE, PREMISES CONSIDERED, Plaintiff prays that this Court:

a. enter judgment against Defendants, Salvacion USA and Salvacion International, and in favor of Plaintiff requiring Defendants, Salvacion USA and Salvacion International, to pay over and account to Plaintiff for all gains, profits, and advantages derived from the infringement of its '802 Patent beginning March 4, 2019, based upon manufacture, sales, and/or use of the products in the United States and anywhere in the world, or by way of international commerce with the United States;

b. enter judgment against Defendants, Salvacion USA and Salvacion International, and in favor of Plaintiff, enjoining Defendants Salvacion USA and Salvacion International enjoining them from manufacturing and/or selling the products, either directly or indirectly;

c. enter judgment against Defendants, Salvacion USA and Salvacion International, and in favor of Plaintiff, enjoining Defendants Salvacion USA and Salvacion International from actively inducing others to sell the products, either directly or indirectly;

d. enter judgment against Defendants, Salvacion USA and Salvacion International, and in favor of Plaintiff, enjoining Defendants

Salvacion USA and Salvacion International from exporting the products, either directly or indirectly;

e. enter judgment against Defendants, Salvacion USA and Salvacion International, and in favor of Plaintiff for all costs sustained in connection with the prosecution of this action, including attorney fees;

f. enter judgment against Defendants, Salvacion USA and Salvacion International, and in favor of Plaintiff for enhanced damages due to willful infringement of the '802 Patent; and

g. grant such other and further relief as justice requires.

COUNT TWO — BREACH OF CONTRACT
(As to Defendant Peter Cho)

99. Plaintiff restates every fact and allegation set forth in all preceding paragraphs of this Complaint as if fully set forth herein.

100. Defendant Peter Cho entered into the CDA Agreement (Exhibit 1) with Wahi on March 4, 2019, whereby Trutek agreed to disclose its confidential and proprietary information and trade secrets ("confidential information") to Cho, and in return, Cho agreed to maintain said confidential information in strict confidence and that Trutek would own all unique developments resulting from said confidential information, patentable or not.

101. Defendant Cho ratified said CDA on May 12, 2019 by incorporating it by reference into an "Agreement For Importation, Marketing, Sales & Distribution of Trutek's NasalGuard® Gel -Tube Product in South Korea." (Exhibit 2.)

102. Defendant Cho ratified said CDA on November 6, 2019 by incorporating it by reference into an "Agreement For Importation, Marketing, Sales & Distribution of Trutek's NasalGuard® Gel -Tube Product in Greater China and Vietnam." (Exhibit 3.)

103. Plaintiff Trutek performed its duties under said CDA.

104. Defendant Cho breached the terms and conditions of said CDA by disclosing said confidential information to others, by filing a patent application at the USPTO, and by developing and marketing a product that infringes on Trutek's '802 Patent.

105. Defendant Cho breached the implied warranty of good faith and fair dealing by disclosing said confidential information to others, by filing a patent application at the USPTO, and by developing and marketing a product that infringes on Trutek's '802 Patent.

WHEREFORE, PREMISES CONSIDERED, Plaintiff prays that this Court:

a. enter judgment against Defendant Cho and in favor of Plaintiff for compensatory general damages in amounts to be determined at trial and as are allowed under the statute;

b. enter judgment against Defendant Cho and in favor of Plaintiff requiring Cho to convey and assign all his rights, title, and interests in all unique developments resulting from said confidential information to Trutek;

c. enter judgment against Defendant Cho and in favor of Plaintiff requiring Cho to convey and assign all his right, title, and interest in U.S. Patent Application No. 17/576098, continuations therefrom, and all patents issuing therefrom to Trutek;

d. enter judgment against Defendant Cho and in favor of Plaintiff requiring Cho to convey and assign all his right, title, and interest in International Patent Application No. PCT/US20/55772, continuations therefrom, and all patents issuing therefrom to Trutek;

e. enter judgment against Defendant Cho and in favor of Plaintiff enjoining Cho from continuing his activities related to all unique developments resulting from said confidential information; and

f. grant such other and further relief as justice requires.

COUNT THREE — CONCEALMENT
(as to Defendant Peter Cho)

106. Plaintiff restates every fact and allegation set forth in all preceding paragraphs of this Complaint as if fully set forth herein.

107. Defendant Peter Cho had a duty to disclose to Trutek that it was making, using, offering to sell, selling, and exporting the Accused Product, which represents a developed improvement to the Confidential and Proprietary Intellectual Property owned by Trutek in violation of the terms and conditions of the CDA entered into by Cho on March 4, 2019.

108. Defendant Peter Cho breached his duty to Plaintiff by not disclosing to Trutek that he was developing, making, using, offering to sell, selling, and exporting the Accused Product.

109. When Plaintiff disclosed its confidential and proprietary information regarding its intellectual property, Plaintiff reasonably relied on the fact that Peter Cho would not develop, make, use, offer to sell, sell, or export any developments or improvements to Trutek's intellectual property.

110. Plaintiff's injury was caused by said non-disclosure, which delayed action that Plaintiff might have taken to enjoin Defendants from selling the Accused Product, which directly diminished sales of Trutek's own products.

WHEREFORE, PREMISES CONSIDERED, Plaintiff prays that this Court:

a. enter judgment against Defendant Cho and in favor of Plaintiff for compensatory general damages in amounts to be determined at trial and as are allowed by law;

b. enter judgment against Defendant Cho and in favor of Plaintiff for enhanced damages, attorney fees, interest, and costs; and

c. grant such other and further relief as justice requires.

COUNT FOUR — CONVERSION
(as to all Defendants)

111. Plaintiff restates every fact and allegation set forth in all preceding paragraphs of this Complaint as if fully set forth herein.

112. The CDA entered into by Peter Cho on March 4, 2019 provides that Trutek "shall have sole, complete and irrevocable rights to all ... Improvements, Inventions, and Patents," patentable or not, resulting from the disclosure of Trutek's confidential and proprietary intellectual property to Cho.

113. In violation of the terms and conditions of the CDA, Cho, Gaffar, and Yun filed International Patent Application No. PCT/US20/55772, said PCT international patent application representing an invention derived from Trutek's disclosure of its intellectual property. Cho then caused said PCT international patent application to be assigned to Salvacion USA. Defendant

Cho and Salvacion USA converted said PCT international patent application, which rightfully belongs to Trutek.

114. In violation of the terms and conditions of the CDA, Cho, Gaffar, and Yun filed U.S. Patent Application No. 17/576,098 at the USPTO, said patent application representing an invention derived from Trutek's disclosure of its intellectual property. Cho, Gaffar, and Yun then caused said U.S. patent application to be assigned to Salvacion USA. Defendants Cho, Gaffar, Yun, and Salvacion USA converted said US patent application, which rightfully belongs to Trutek.

115. The Accused Product, which was developed, manufactured, offered for sale, and sold throughout the world by all defendants was derived from and protected under patents potentially issuing from said PCT international patent application and from said U.S. patent application. The Accused Product and all profits and benefits therefrom belong to Trutek as specified in the Confidential Disclosure Agreement.

116. All Defendants converted the profits and benefits from the sales of the Accused Product in the United States and worldwide.

WHEREFORE, PREMISES CONSIDERED, Plaintiff prays that this Court:

a. enter judgment against Defendants Cho, Gaffar, and Yun in favor of Plaintiff for damages incurred by Plaintiff due to said Defendants' conversion of said PCT international patent application and said U.S. patent application;

b. enter judgment against Defendant Salvacion USA and in favor of Plaintiff for damages incurred by Plaintiff due to conversion of said PCT international patent application and said U.S. patent application by Salvacion USA;

c. in the alternative to Paragraph (b) *supra*, enter judgment against Defendant Salvacion USA and in favor of Plaintiff compelling it to assign said PCT international patent application and said U.S. patent application to Trutek;

d. enter judgment against all Defendants for conversion of profits and benefits from the sales of the Accused Product in the United States and worldwide; and

e. grant such other and further relief as justice requires.

COUNT FIVE — VIOLATION OF 18 U.S.C. § 1832
Theft of Trade Secrets
(as to Cho, Gaffar, Yun, Salvacion USA, Salvacion International)

117. Plaintiff restates every fact and allegation set forth in all preceding paragraphs of this Complaint as if fully set forth herein.

118. Trutek develops and markets products that include nasal gels and nasal sprays that inhibit infection of individuals from inhalation of harmful particles (*e.g.,* viruses, bacteria, and fungi) into the individual's respiratory system. Although a number of patents have been issued on Trutek's technology, much still remains as trade secrets (*e.g.* ,manufacturing methodology, efficacy, ingredients, level of electrostatic charged necessary and sufficient to be effective, *etc.*), These trade secret items were never disclosed to the public. Trutek has maintained and does maintain these items zealously as trade secrets.

119. In 2019 and 2020, Peter Cho was a principle of Jintec America, Inc., ("Jintec"), a New Jersey corporation. Jintec's corporate address is the same as that of Salvacion USA.

120. On March 4, 2019 Peter Cho, having the stated desire for Jintec to become a distributor of Trutek's products in Korea, entered into the CDA (Exhibit 1). That agreement provided that Trutek will disclose its intellectual property technology (including its trade secrets) to Cho, and in consideration Cho will not disclose said technology to third parties or use said technology for any other purpose than to serve as distributor for Trutek's products.

121. In reliance on the terms and conditions of the CDA and Cho's stated intention for Jintec to become Trutek's distributor, Trutek disclosed its technology to Cho.

122. On August 31, 2020, Cho, Gaffar, and Yun filed U.S. Provisional Patent Application No. 63/103,881, which served as a priority document for International Patent Application No. PCT/US20/55772 filed on October 15, 2020, which in turn served as a priority document for U.S. Patent Application No. 17/576,098 filed on January 14, 2022, for "Antiviral Composition and Use of the Same." The U.S. Patent application was assigned to Salvacion USA. Said patent applications all utilized trade secrets that Trutek disclosed to Cho.

123. Cho, Gaffar, Yun, and Salvacion USA utilized Trutek's trade secrets in violation of 18 U.S.C. § 1832(a) without permission from Trutek to file the aforementioned patent applications with intent to convert Trutek's trade secrets, that are related to a product used in or intended for use in interstate or foreign commerce to the economic benefit of Salvacion USA and Salvacion International rather than Trutek, and intending or knowing that the offense will injure Trutek.

124. Salvacion USA and Salvacion International began making, offering for sale, selling, and exporting the Asserted Product, which were derived from the

technology in the aforementioned patent applications, and which utilized Trutek's trade secrets.

125. Cho, Gaffar, Yun, Salvacion USA, and Salvacion International conspired with each other in a global enterprise (*i.e.,* the Salvacion Enterprise) in violation of 18 U.S.C. § 1832 (a)(5) to commit offenses described in 18 U.S.C. §§ 1832(a), Paragraphs (1), (2), and (3) and one or more said Defendants performed acts, which were part of the conspiracy.

126. **WHEREFORE, PREMISES CONSIDERED**, Plaintiff prays that this Court:

a. enter judgment against Defendants Cho, Gaffar, Yun, Salvacion USA, and Salvacion International and in favor of Plaintiff for damages as prescribed in 18 U.S.C. § 1832(b); and

b. grant such other and further relief as justice requires.

COUNT SIX — VIOLATION OF N.J.S.A § 56:15-1 *et seq*.
The New Jersey Trade Secrets Act ("NJTSA")
(as to Cho, Gaffar, Yun, Salvacion USA, Salvacion International)

127. Plaintiff restates every fact and allegation set forth in all preceding paragraphs of this Complaint as if fully set forth herein.

128. Trutek develops and markets products that include nasal gels and nasal sprays that inhibit infection of individuals from inhalation of harmful

particles (*e.g.,* viruses, bacteria, and fungi) into the individual's respiratory system. Although a number of patents have been issued on Trutek's technology, much still remains as trade secrets (*e.g.,* manufacturing methodology, efficacy, formulae, unpatented inventions, level of electrostatic charged necessary and sufficient to be effective, *etc.*). These trade secret items were never disclosed to the public. Trutek has maintained and does maintain these items zealously as trade secrets.

129. These secrets derive independent economic value to Trutek from not being generally known to, and not being readily ascertainable by proper means to other persons who can obtain economic value from their disclosure or use.

130. On March 4, 2019 Peter Cho, having the stated desire for Jintec to become a distributor of Trutek's products in Korea, entered into the CDA Agreement (Exhibit 1). That agreement provided that Trutek will disclose its intellectual property technology (including its trade secrets) to Cho, and in consideration Cho will not disclose said technology to third parties or use said technology for any other purpose than to serve as distributor for Trutek's products.

131. In reliance on the terms of the Confidential Disclosure Agreement and Cho's stated intention for Jintec to become Trutek's distributor, Trutek disclosed its

technology to Cho. Cho knew that the information disclosed to him by Trutek contained trade secrets.

132. Cho had a duty to maintain said trade secrets in confidence and not to use said trade secrets for any purpose other than for Jintec to act as a distributor for Trutek products in Korea, Greater China, and Vietnam.

133. In breach of that duty and in bad faith, Cho disclosed Trutek's trade secrets to Gaffar and Yun, and used said trade secrets to benefit Salvacion USA and Salvacion International without express or implied permission from Trutek and in violation of the NJTSA.

WHEREFORE, PREMISES CONSIDERED, Plaintiff prays that this Court enter judgment against Defendants Cho, Gaffar, Yun, Salvacion USA, and Salvacion International and in favor of Plaintiff:

a. for damages caused by misappropriation as well based as the amount the misappropriating party was unjustly enriched by the misappropriation to the extent that it exceeds the actual loss; and

b. for punitive damages that are twice the amount of the actual damages;

c. for reasonable costs and legal fees;

d. enjoining Defendants from continuing to use Trutek's trade secrets; and

e. grant such other and further relief as justice requires.

COUNT SEVEN — UNJUST ENRICHMENT
(as to all Defendants)

134. Plaintiff restates every fact and allegation set forth in all preceding paragraphs of this Complaint as if fully set forth herein.

135. All Defendants are participants in a global enterprise (the "Salvacion Enterprise") that exploits and receives profits from sales of the Accused Product.

136. Individual Defendants Cho, Gaffar, and Yun receive or are entitled to receive monetary benefits from their participation in the Salvacion Enterprise.

137. The Salvacion Enterprise is liable for the acts of Cho, Gaffar, and Yun based on the principle of *respondeat superior*.

138. Several patent applications (U.S. and international) are developments derived from disclosure of proprietary information by Trutek to Cho.

139. According to the CDA entered into by the parties on March 4, 2019 (Exhibit 1), said patent applications and patents issuing therefrom represent intellectual property rightfully belonging to Trutek.

140. According to the CDA, the Accused Product, and all monies derived from exploitation and sales of the Accused Product by the Salvacion Enterprise belong to Trutek.

141. Defendants Salvacion USA, Salvacion International, Salvacion Co., Ltd., Salvacion R&D Center, Biosure, and Inmobiliaria La Salvacion, R.D. all profited from the sales of the Accused Product that rightfully belonged to Trutek, and were thus unjustly enriched.

142. Trutek never received any royalties or monies from the Salvacion Enterprise derived from exploitation and sales of the Accused Product.

143. The Salvacion Enterprise and all Defendants were unjustly enriched from its exploitation and sales of the Accused Product.

WHEREFORE, PREMISES CONSIDERED, Plaintiff prays that this Court:

a. enter judgment against all Defendants and in favor of Plaintiff requiring Defendants to remit to Trutek all monies derived from their sales and exploitation of the Accused Product; and

b. grant such other and further relief as justice requires.

COUNT EIGHT — CIVIL CONSPIRACY
(as to All Defendants)

144. Plaintiff restates every fact and allegation set forth in all preceding paragraphs of this Complaint as if fully set forth herein.

145. Defendants Cho, Gaffar, and Yun made an agreement to file patent applications based on trade secrets misappropriated from Trutek and to develop the Accused Product that infringes Trutek's '802 Patent.

146. All Defendants made an agreement to form the Salvacion Enterprise for the purpose of exploiting and profiting from sales of the Accused Product, which both rightfully belongs to Trutek, and which infringes Trutek's '802 Patent.

147. All Defendants made an agreement to misappropriate Trutek's trade secrets in a tortious effort to develop, patent, make, exploit, sell, and export the Accused Product, which both rightfully belongs to Trutek, and which infringes Trutek's '802 Patent. In doing so, all Defendants formed an Enterprise to convert monies rightfully due to Trutek, to interfere with Trutek's prospective economic advantage, and to engage in unfair business practices.

148. The tortious acts were committed by the Defendants and the Salvacion Enterprise against the Plaintiff in furtherance of the agreement.

149. Plaintiff suffered economic losses as a result of said tortious acts.

WHEREFORE, PREMISES CONSIDERED, Plaintiff prays that this Court enter judgment against all Defendants and in favor of Plaintiff:

a. holding all Defendants jointly and severally liable for damages sustained by Plaintiff as a result of the conspiracy;

b. awarding lost profits and other damages sustained by Trutek as a result of the conspiracy; and

c. granting such other and further relief as justice requires.

COUNT NINE — FRAUD
(as to All Defendants)

150. Plaintiff restates every fact and allegation set forth in all preceding paragraphs of this Complaint as if fully set forth herein.

151. Defendants conducted a fraudulent scheme to extract tribute from Plaintiffs. Defendants willfully and knowingly made, or caused to be made, affirmative misrepresentations of material facts in the furtherance of this scheme. Cho promised Wahi not to disclose or use any of Trutek's intellectual property disclosed to him by Wahi, and he also promised that any developments resulting from Trutek's disclosures to him would belong to Trutek. All Defendants were complicit in Cho's misrepresentations. Trutek relied on Defendants' representations, and they were false. Defenants also willfully and knowingly concealed material facts from Plaintiff. Defendants knowingly and intentionally concealed from Trutek that Defendants were developing, making, offering to sell and selling developments and

improvements to Trutek's intellectual property disclosed to Cho. Defendants also intentionally and knowingly concealed the fact that they filed patent applications on improvements to Trutek's intellectual property disclosed to Cho. Defendants knew the falsity of the misrepresentations at the time these misrepresentations were made. Defendants also knew the material nature of the facts that they willfully concealed from Plaintiff, and that Defendants ought to have disclosed these facts at that time to Plaintiff. Defendants had superior knowledge not available to Plaintiff; as such, they had the duty to disclose the facts. Plaintiff relied upon Defendants representations and was unaware of the falsity or misleading nature of the representations. Plaintiff's reliance was reasonable under the circumstances. As a result of such reliance, Plaintiff sustained damages.

152. By engaging in the conduct described above, Defendants committed a fraud upon Plaintiff.

153. Moreover, Defendants' wanton conduct was systematic, in reckless disregard of their statutory and other duties, tantamount to criminal indifference to civil obligations, and unconscionable.

WHEREFORE, PREMISES CONSIDERED, Plaintiff prays that this Court:

d. enter judgment against Defendants and in favor of Plaintiff for compensatory, punitive, statutory and/or treble damages in amounts to be determined at trial and as are allowed under the statute;

e. enter judgment against Defendants and in favor of Plaintiff for an injunction prohibiting the Defendants' wrongful actions;

f. enter judgment against Defendants and in favor of Plaintiff for all costs sustained in connection with the prosecution of this action, including attorneys' fees; and

g. grant such other and further relief as justice requires.

COUNT TEN – VIOLATION OF 18 U.S.C. §§ 1961-1968
Racketeer Influenced and Corrupt Organizations Act ("RICO")
(As to All Defendants)

154. Plaintiff restates every fact and allegation set forth in all preceding paragraphs of this Complaint as if fully set forth herein.

155. The association of Defendants and others whose identities are known only to the Defendants at this time (cumulatively, the "Conspirators"), constituted an Enterprise (*i.e.,* the Salvacion Enterprise) within the meaning of 18 U.S.C. §1961(c), which Enterprise was engaged in, and whose activities affected, interstate and foreign commerce. This Salvacion Enterprise was

continuous in that it lasted more than two years, had an ascertainable structure, and was distinct from the predicate offenses alleged herein.

156. Each Defendant is a person within the meaning of 18 U.S.C. §1961(3).

157. At all relevant times, Salvacion USA constitutes an "Enterprise" within the meaning of 18 U.S.C. §§ 1961(4) and 1962(c). At all relevant times, the Salvacion USA was engaged in, and/or its activities affected, interstate commerce and/or foreign commerce within the meaning of 18 U.S.C. § 1962(c). At all relevant times, Defendants held a position in Salvacion USA as well as participated in the operation, management, and directed the affairs of the Salvacion USA. Salvacion USA, as alleged herein, was not limited to Defendants' predicate acts and has activities extending beyond Defendants' racketeering activity.

158. At all relevant times, Salvacion International constitutes an "Enterprise" within the meaning of 18 U.S.C. §§ 1961(4) and 1962(c). At all relevant times, the Salvacion International was engaged in, and/or its activities affected, interstate commerce and/or foreign commerce within the meaning of 18 U.S.C. § 1962(c). At all relevant times, Defendants held a position in Salvacion International as well as participated in the operation, management, and directed the affairs of the Salvacion International. Salvacion International, LLC, as alleged herein, was not limited to Defendants'

predicate acts and has activities extending beyond Defendants' racketeering activity.

159. At all relevant times, Biosure Global constitutes an "Enterprise" within the meaning of 18 U.S.C. §§ 1961(4) and 1962(c). At all relevant times, Biosure Global was engaged in, and/or its activities affected, interstate commerce and/or foreign commerce within the meaning of 18 U.S.C. § 1962(c). At all relevant times, Defendants held a position in Biosure Global as well as participated in the operation, management, and directed the affairs of Biosure Global. Biosure Global as alleged herein, was not limited to Defendants' predicate acts and has activities extending beyond Defendants' racketeering activity.

160. Defendant Cho, is one of the willful, active participates in the Salvacion Enterprise. He is a co-founder of Salvacion USA, and is an owner/officer of some of the other related corporate enterprises, was in charge of its day-to-day operations. As such, he was one of the masterminds of the Salvacion Enterprise who set up, orchestrated and supervised the entire racketeering scheme at issue. While he was not the only mastermind, the other Conspirators acted through various corporate entities, and they functioned with the same intent.

161. Defendant Gaffar is one of the willful, active participates in the Salvacion Enterprise. He is the co-founder of Salvacion USA, Inc. and is an owner/officer of some of the other related corporate enterprises, was in charge of its day-to-day operations. As such, he was one of the masterminds of the Salvacion Enterprise who set up, orchestrated and supervised the entire racketeering scheme at issue. While he was not the only mastermind, the other Conspirators acted through various corporate entities, and they functioned with the same intent.

162. Defendant Yun is one of the willful, active participates in the Salvacion Enterprise. He is the co-founder of Salvacion USA, Inc. and is an owner/officer of some of the other related corporate enterprises, was in charge of its day-to-day operations. As such, he was one of the masterminds of the Salvacion Enterprise who set up, orchestrated and supervised the entire racketeering scheme at issue. While he was not the only mastermind, the other Conspirators acted through various corporate entities, and they functioned with the same intent.

163. The remaining Defendants are corporate entities through which the Salvacion Enterprise functioned, and through which the underlying racketeering scheme was carried out.

164. Defendants' scienter is established from their pattern and practices at issue

and the centrality of these practices to their entire business.

165. Defendants participated and conspired with others (including others whose identities are known only to the Defendants at this time) to participate, in the of the aforementioned Salvacion Enterprise through a pattern of racketeering activity, as more fully set forth below, all in violation of 18 U.S. C. §1962(C).

166. Cho and Wahi entered into a binding agreement (the CDA) whereby Wahi would disclose Trutek's confidential information to Cho, and in return, Cho would not disclose said confidential information to any third party nor would Cho use it for any purpose unless authorized to do so in writing by Wahi. Cho further agreed that Trutek will have "sole and irrevocable rights to all such improvements, inventions and Patents without any further verbal or written authorization from" Trutek.

167. Relying on assurances from Cho not to disclose or use Trutek's proprietary intellectual property, including Trutek's trade secrets, Trutek entered into exclusive distribution agreements with Jintec for South Korea, Vietnam, and Greater China.

168. Wahi disclosed its confidential and proprietary information and technology to Cho. Shortly after Trutek entered into said distribution agreements with Jintec, in a scheme to defraud Trutek by converting Trutek's intellectual

property, Cho disclosed Trutek's confidential information to others, and used it for his own purposes without prior authorization from Wahi.

169. In furtherance of his scheme to defraud Trutek, Cho became involved as a principal of a company that produces a competitive product based on Trutek's technology.

170. In furtherance of his scheme to defraud Trutek, Cho failed to honor his contractual obligation by allowing patent applications for Trutek's technology to be filed electronically at the USPTO in his name and to be assigned to Salvacion USA instead of to Trutek. Filing of the patent applications and assignment to Salvacion USA was performed over the Internet using electronic communications.

171. These actions by Cho constituted wire fraud as defined in 18 U.S.C. § 1343.

172. In furtherance of his scheme to defraud Trutek, Cho knowingly and intentionally converted Trutek's proprietary technology for his own purposes and stole Trutek's trade secrets for his own purposes.

173. In furtherance of his scheme to defraud Trutek, Cho knowingly conspired with other individuals and companies within the Salvacion Enterprise to utilize Trutek's proprietary technology for their own profit.

174. In furtherance of his scheme to defraud Trutek, Cho knowingly and willfully

induced those within the Salvacion Enterprise to infringe upon the claims of Trutek's '802 Patent.

175. In a scheme to defraud Trutek, Gaffar knowingly conspired with Cho allowing patent applications for Trutek's technology to be filed electronically at the USPTO in his name and to be assigned to Salvacion USA instead of to Trutek. Filing of the patent applications and assignment to Salvacion USA was performed over the Internet using electronic communications.

176. These actions by Gaffar constituted wire fraud as defined in 18 U.S.C. § 1343.

177. In furtherance of their scheme to defraud Trutek, Gaffar knowingly conspired with Cho to utilize Trutek's proprietary confidential information to make, use, and sell a product in the United States and worldwide that infringes on Trutek's '802 Patent in violation of 35 U.S.C. § 271(a).

178. In furtherance of their scheme to defraud Trutek, Gaffar was complicit with Cho in developing the Covixyl product and in filing a patent application for the same. The product and the patent application represent improvements over Trutek's proprietary confidential information, and they rightfully belong to Trutek.

179. In furtherance of their scheme to defraud Trutek, Gaffar knowingly

conspired with other individuals and companies within the Salvacion Enterprise to utilize Trutek's proprietary technology for their own profit.

180. In furtherance of their scheme to defraud Trutek, Gaffar knowingly and willfully induced those within the Salvacion Enterprise to infringe upon the claims of Trutek's '802 Patent.

181. In furtherance of their scheme to defraud Trutek, Yun was complicit with Cho in developing the Covixyl product, in filing patent applications at the USPTO for the same in his name, and in assigning said patent applications to Salvacion USA. The product and the patent application represent improvements over Trutek's proprietary confidential information, and they rightfully belong to Trutek. Filing said patent applications at the USPTO and assigning said patent applications to Salvacion USA was done electronically over the Internet.

182. These actions by Yun constituted wire fraud as defined in 18 U.S.C. § 1343.

183. In furtherance of their scheme to defraud Trutek, Yun knowingly conspired with other individuals and companies within the Salvacion Enterprise to utilize Trutek's proprietary technology for their own profit.

184. In furtherance of their scheme to defraud Trutek, Yun knowingly and willfully induced those within the Salvacion Enterprise to infringe upon the claims of Trutek's '802 Patent.

185. Salvacion USA infringes the claims of the '802 Patent by making, using, and selling an infringing product Covixyl in violation of 35 U.S.C. § 271(a).

186. Infringement of the '802 Patent by Salvacion USA is willful because at least one of its principals was aware of the '802 Patent and its technology before said infringement occurred.

187. In furtherance of their scheme to defraud Trutek, Salvacion USA knowingly induced others to infringe on the claims of the '802 Patent.

188. In furtherance of their scheme to defraud Trutek, Salvacion USA knowingly conspired with other entities within the Salvacion Enterprise to profit from technology that rightfully belongs to Trutek and not to Salvacion USA.

189. In furtherance of the scheme to defraud Trutek, Salvacion USA intentionally and fraudulently claimed publicly that it had the right to market the Accused products.

190. In furtherance of the scheme to defraud Trutek, Salvacion International infringes the claims of the '802 Patent by making, using, and selling an infringing product Covixyl in violation of 35 U.S.C. § 271(a).

191. Infringement of the '802 Patent by Salvacion International is willful because at least one of its principals was aware of the '802 Patent and its technology before said infringement occurred.

192. In furtherance of the scheme to defraud Trutek, Salvacion International

knowingly conspired with other entities within the Salvacion Enterprise to profit from technology that rightfully belongs to Trutek and not to Salvacion International.

193. In furtherance of the scheme to defraud Trutek, Salvacion USA and International sold Covixyl products to customer end-users throughout the entire United States over the Internet.

194. In furtherance of the scheme to defraud Trutek, payments for the sales to the members of the Salvacion Enterprise were executed *via* wire communications.

195. These actions by Salvacion USA and Salvacion International constituted wire fraud as defined in 18 U.S.C. § 1343.

196. In furtherance of the scheme to defraud Trutek, deliveries of the Covixyl products to customer end-users were made using United States mail services.

197. These actions by Salvacion USA and Salvacion International constituted mail fraud as defined in 18 U.S.C. § 1341.

198. As an instance of sale to end users, Nitin Kumar and Keith Altman purchased Covixyl products from the Salvacion Enterprise, and paid for these products over the Internet. Delivery of said products to these individuals was made using United States mail services.

199. These actions by Salvacion USA and Salvacion International constituted

wire fraud as defined in 18 U.S.C. § 1343 and mail fraud as defined in 18 U.S.C. § 1841.

200. In furtherance of the scheme to defraud Trutek, Biosure Global intentionally conspired with other entities within the Salvacion Enterprise to profit from technology that rightfully belongs to Trutek and not to Biosure Global.

201. In furtherance of the scheme to defraud Trutek, Each member of the Salvacion Enterprise conspired with all other members to deprive Trutek of its technology. The members of the Salvacion Enterprise intentionally, knowingly, and fraudulently advertised electronically online offering to sell a product that it did not own and that belongs to Trutek. When they did sell their product rightfully belonging to Trutek, they accepted payment for their fraudulent activities electronically.

202. Each participant knew, expected, reasonably foresaw, and intended that the facilities of their actions affecting interstate and foreign commerce would be used in furtherance of the racketeering scheme, and that such use was an essential part of the scheme.

203. The Conspirators willfully and with intent to mislead concealed material facts and made affirmative misrepresentations of material facts to Plaintiff.

204. Plaintiff relied upon Defendants; misrepresentations, and such reliance was reasonable.

WHEREFORE, PREMISES CONSIDERED, Plaintiff prays that this Court enter judgment against all Defendants and in favor of Plaintiff:

a. holding all Defendants jointly and severally liable for damages sustained by Plaintiff as a result of the conspiracy;

b. for compensatory, punitive, statutory, and/or treble damages in amounts to be determined at trial and as allowed under the statute;

c. requiring Defendants to pay over and account to Plaintiff for all gains, profits, and advantages derived from sales of the Covixyl and related products within the United States and all foreign countries;

d. enjoining Defendants from manufacturing and/or selling Covixyl and related products indefinitely and in accordance with the signed CDA and '802 Patent;

e. enjoining Defendants from actively inducing others to make or sell the Covixyl and related products;

f. prohibiting Defendants other wrongful actions;

g. awarding all costs sustained in connection with the prosecution of this action, including attorneys' fees; and

h. granting such other and further relief as justice requires.

DEMAND FOR DISCOVERY OF INSURANCE COVERAGE

Pursuant to Defendants' discovery obligations, demand is made that all Defendants disclose to the Plaintiff whether or not there are any insurance agreements or policies under which any person or firm carrying on an insurance business may be liable to satisfy part or all of a judgment which may be entered in this action or indemnify or reimburse for payments made to satisfy the judgment and provide Plaintiff with true copies of those insurance agreements or policies, including, but not limited to, any and all declarations sheets. This demand shall include and cover not only primary coverage, but also any and all excess, catastrophe and umbrella policies.

DEMAND FOR A JURY TRIAL

Plaintiff hereby demands a trial by jury of all issues triable of right by a jury in this action.

Dated: July 11, 2023

Respectfully submitted,

/s/ Solomon Radner
Solomon Radner (NJ SBN 283502018)
LAW OFFICE OF KEITH ALTMAN
33228 West 12 Mile Road, Suite 375
Farmington Hills, MI 48334
Telephone: (248) 987-8929
Facsimile: (248) 213-9907
solomonradner@kaltmanlaw.com

EXHIBIT 1

Confidential Disclosure Agreement (CDA Wahi/Cho)

CONFIDENTIAL DISCLOSURE AGREEMENT

THIS Agreement is entered into by and between Ashok Wahi, President, Trutek Corp, or their designees (hereinafter the Principal) and Mr. Peter Cho as President, Jintec America Inc. 210, Sylvan Ave., #24, Englewood Cliffs, NJ 07632 and as an individual residing at 534A Hillside Avenue, Palisades Park, NJ 07650 as of March 4, 2019 (hereinafter the Disclosee).

WHEREAS, the Principal and the Disclosee wish to further discussions regarding NasalGuard© with special features, attributes and additional claims, Miracle Under-Eye™, NasalGuard® Unscented, NasalGuard® Allergie Block®, NasalGuard Cold & Flu Block®, NasalGuard® Multi Acting™, NasalGuard® Single Application Sachets, NasalGuard MF, NasalGuard Airborne Particle Blocker, NasalGuard Personal Air-Filter Gel, NasalGuard Particle Blocking Gel, Anti-Stat Enhanced Mask™, NasalGuard Wipes™, NasalGuard Allergie Wipes™, NasalGuard Cold & Flu Wipes™, Skin and Hair super conditioners, Truteks®Skin and Truteks© skin care products, electrostatically charged nasal multipurpose products, nasal application (anti-stat) diagnostic products and, associated Technologies and Methodologies, Patented and Pending Patent Applications, Chloraseptic Allergen Block and Little Allergies Allergen Block, Eisai Crystal Veil, Eisai Crystal Veil Cool, Nitto Nuru Mask, Nitto NasalGuard, including but not limited to nasal application product lines such as gels, pre-moistened products for e.g. applicators, swabs, wipes, etc., sticks, nasal sprays, nasal washes, surgical masks, multi-acting/integrated products, etc. and all other Trutek products (hereinafter the "project"): and

WHEREAS, in order to further such discussions, it will be necessary for the Principal to disclose the Disclosee certain data, samples and information relating to the project which it considers to be confidential and proprietary; and

WHEREAS, the Disclosee agrees to receive such information regarding the "project" in accordance with the terms and conditions contained herein and use it specifically and exclusively for the Principal.

NOW, THEREFORE, in consideration of the mutual benefits in furthering the interests of the parties the parties agree as follows:

1. As used herein, "Confidential Information" shall mean all data, sample information relating to the "project" hereafter disclosed by the Principal to the Disclosee except any documented information that is rightfully in Disclosee's possession prior to the date of this Agreement evidenced by pre-dated written reports and correspondence.

2. The Disclosee agrees that it will maintain all Confidential Information in strict Confidence and that it will not permit Confidential Information in its possession to be disclosed to any third party or used for any purpose not authorized by the Principal in writing.

3. Upon request by the Principal, the Disclosee will return all Confidential Information to The Principal and destroy or erase all additional copies and recordings thereof. Notwithstanding the foregoing, the obligations of confidentiality and non-use established herein shall continue in full force and effect for a period of 10 years from the date hereof.

4. The obligations contained in this Agreement shall extend to and be binding upon any employee or affiliate of the Disclosee, who has access to Confidential Information pursuant to this Agreement. The Disclosee shall obtain the agreement of those employees and affiliates who are granted access to the Confidential Information to comply with the terms hereof. Under no circumstances will the Disclosee attempt to profit from the project in any form other than through an agreement with the Principal.

5. All unique developments, Inventions and Improvements, patentable or not, as a result Disclosee's involvement with the "Project" shall belong to the Principal. The Principal shall have sole, complete and irrevocable rights to all such improvements, Inventions and Patents without any further verbal or written authorization from the Disclosee. The Disclosee's proprietary, patented or copyrighted information, data or processes will not be affected by this agreement.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives on date written above.

Ashok Wahi s/a
Ashok Wahi (The Principal)
President, Trutek Corp.

Witnessed by:

3/4/19
Peter Cho (The Disclosee)
President, Jintec America Inc.

3/4/19
Witnessed by:

EXHIBIT 2

May 12th Agreement
(South Korea - Trutek/Jintec)

Agreement

For Importation, Marketing, Sales & Distribution of
Trutek's NasalGuard® Gel -Tube Product in South Korea

This Agreement is entered into on this 12th day of May, 2019 between Trutek Corp., a New Jersey (NJ) Corporation, with its registered office at 465 Somerville Road, Basking Ridge, NJ 07920, USA (hereafter "Trutek") and Jintec America, Inc. 210 Sylvan Avenue # 24 Englewood Cliffs, NJ 07632 (hereafter "Jintec")

WHEREAS, Trutek is the lawful and legal owner of the US registered trademarks of Truteks and NasalGuard for NasalGuard® (Year Round Topical) Gel - Tube Product (hereafter "Product") and desires to grant Jintec an exclusive license for Importation [in Primary Container i.e. filled & sealed tubes] for Secondary Packaging, Marketing (advertising & promotion), Sales, and Distribution of NasalGuard® products in South Korea.("Territory")

WHEREAS, Jintec, having conducted sufficient due diligence, desires to be licensed by Trutek to fulfill all obligations granted by Trutek under this Agreement;

WHEREAS, both parties have had the opportunity to seek independent legal counsel for this Agreement, have read and understood all the terms of the agreement, have signed this Agreement freely and voluntarily, without any duress or coercion, and have agreed to abide by the terms of this Agreement;

NOW, THEREFORE, in mutual benefits the parties agree as follows:

I. **Confidentiality**: Any data, documentation, information, literature or publications in any and all formats; and samples or materials submitted to Jintec by Trutek prior and during the Term of this Agreement shall be bound by the terms of the executed Confidential Disclosure Agreement executed on March 4, 2019 (Attachment I") for a minimum period of ten years upon termination of this Agreement.

II. **Trade Secrets, Trademarks, and Patent Protection:**

(a) Trutek does not grant and Jintec does not claim and will not claim any rights whatsoever with respect to Trutek's Trade Secrets and Intellectual Property (hereafter "IP"), and Jintec hereby acknowledges Trutek's exclusive right and title in the Territory and elsewhere to the Products and Trutek's Trade Secrets and Intellectual Property. The phrase "Trutek's Trade Secrets and Intellectual Property" refers to Trutek's trademarks, patents and patents-pending, goodwill, trade names, trade secrets, manufacturing and selling processes, knowhow and techniques, secret formulae, copyrights, designs, and other materials of any kind whatsoever employed in connection with the manufacture, assembly, packaging, offering for sale, advertisement, promotion and sale of the Products. In addition, Jintec shall not attempt to manufacture or commission the manufacturing of the Trutek's product NasalGuard herein or any products, which shall be developed by Trutek in the future.

(b) Jintec shall not register any of Trutek's trademarks, trade names, designs or copyrights, or obtain any patents covering the Products in the Territory covered by this Agreement or anywhere else.

(c) Upon execution of this Agreement, Jintec may register Trutek's trademarks (similar or equivalent of Truteks and NasalGuard and others) in connection with the sales of the Products with the consent of Trutek, which will not be unreasonably withheld provided such trademarks are assigned to Trutek under the Clause II (d). Any such filing for trademark registration for launch of the Products shall be done no later than 30 days from the date of signing this Agreement by a qualified/accredited trademark attorney in South Korea retained and paid for by Jintec. Jintec is only permitted to use during the term of this Agreement the trademarks of the Product, in accordance with the provisions of this Agreement, and any and all use by Jintec of said trademark shall inure to the benefit of Trutek, and Jintec shall acquire no rights in said marks through such use.

(d) In the event that this Agreement is terminated, Jintec shall not use these trademarks on the Products, and Jintec shall assign and return all said trademarks to Trutek with Trutek's payment of registration fees and trademark attorney's fees, sincerely and diligently to be mutually negotiated by Trutek and Jintec.

(e) Upon execution of this Agreement, Trutek shall immediately file the patent of PCT/US2017 /048386 in Korea.

III. **Initial Term:** The parties have agreed to an initial term of five years starting from the execution of this Agreement. This Agreement shall be automatically renewable unless a written notice to terminate is given at least 90 days prior to the expiration of the term by either party to the other. Such termination shall not, however, occur upon Trutek's initiation if Jintec continues to meet the 'minimum' sales requirement stipulated in Clause IX (c) during the term of this Agreement, unless there's a breach by Jintec uncured for 30 days of notification by Trutek.

IV. **Distribution of Products:** The primary container (i.e. filled and sealed tubes) to be packaged in secondary packaging and distributed by Jintec shall include 3.00 gm NasalGuard gel in tubes, bulk-packed for cartoning and secondary packaging by Jintec for importation through commercial sales to consumers in and exclusively for South Korea.

V. **Exclusivity/Territory:** Trutek grants Jintec the license and distribution rights in South Korea. No sales are permitted outside South Korea. Any violation of the 'sales territory' not reversed within 30 days from notification shall be a cause of the termination of this Agreement.

VI. **Use of Trutek's NasalGuard® Trademark and Intellectual Property Rights by Jintec:**

(a) Jintec shall use Trutek's and NasalGuard trademarks (Trutek's registered trademark) on the products & carton graphics and advertisement & promotional materials. Upon receipt of Trutek's prior approval, NasalGuard may be co-branded with Jintec's trademark/brand name as long as both brand names are indicated/publicized in substantially equivalent prominence and placements.

(b) Jintec shall be responsible to supply the design (graphic artwork & mechanical) of the Primary Container i.e.; tube, the secondary packaging including carton, labeling and regulatory compliance, packaging, through distribution subject to approval of all copies, ads, promotional materials explicitly, conspicuously and prominently indicating NasalGuard® trademark on all such materials. Jintec shall have an exclusive and automatic use of rights for the NasalGuard trademark during the entire term of its Agreement with Trutek. Jintec will respect the Intellectual Property Rights of Trutek Corp. and with due prominence indicate 'Created with NasalGuard Patented Technology' and some verbiage to that extent for Trutek Corp's "IP" rights on the product carton and all advertising and promotional materials.

VII. **License Fees:** Trutek grants Jintec an exclusive license for Importation [in Primary Container i.e. filled & sealed tubes] for Secondary Packaging, Marketing (advertising & promotion), Sales, and Distribution of NasalGuard® products in South Korea, ("Territory") as long as this Agreement is valid. For this License, Jintec has agreed to pay Trutek a License Fee of USD 75,000 in three installments as follows:

i). $25,000 paid upon signing of this Agreement.
ii). $ 25,000 paid on the 30th day from signing this Agreement, and;
iii). the balance $25,000 paid on the date of submission of test reports described in VIII (f) or the 90th day from signing this Agreement whichever occurs first.

VIII. Reformulation of NasalGuard Gel:

To comply with the requirements as regulated by the relative government authorities including the Ministry of Food and Drug Safety, the Republic of Korea ("MFDS"), Trutek will undertake R&D to develop a product gel permissible for sale in South Korea. The reformulation will have the following essential features:

(a) Current MFDS, South Korea requirements with respect to NasalGuard Gel's ingredients' 'Positive' and 'Negative' Lists entails revising gel composition to comply with three such ingredients' requirements.

(b) It has been conveyed by Jintec and agreed to by Trutek to re-formulate the gel in accordance with limitations ingredients as follows:

i) Behentrimonium Chloride: < 0.10%
ii) Phenoxyethanol: <1.00%
iii) Potassium Sorbate: <0.60%
iv) Methyl Paraben: <0.5%
v) Benzethonium Chloride: <0.05%
vi) Bezalknonium Chloride:<0.05%

(c) Trutek's gel re-formulation scope of work will include providing a safe and efficacious NasalGuard product gel to Jintec substantially equivalent to the one successfully marketed throughout the world for the past 15 years. The gel has an exemplary safety profile with zero 'adverse event' reported so far.

(d) Reasonable quantity of re-formulated gel, upon success of measured cationic strength and physical properties, manually sealed with approximate 1.5gm in available tubes will be delivered to Jintec for testing purpose to comply with the requirements of the related government authorities including MFDS. The reformulation shall be completed within 60 days from execution of this Agreement.

(e) Any stability test (s), in addition to Trutek's own lab, may be conducted by and at Jintec's discretion and cost at, any third-party facility/lab of Jintec's choosing.

(f) The Safety and Efficacy tests conducted by third party, independent and experienced and well versed with NasalGuard gel products will be conducted, at Trutek's budget, for the following: i) Validate Gel Biocompatibility ii) InVitro Dermal and Ocular Safety, and iii) Particle Capturing Efficiency Lab Bench Test. The signed reports on the above, when completed, but not later than 90 to 150 days from execution of this Agreement, will be submitted to Jintec. In the event Trutek fails to submit the signed reports to Jintec within the designated date, Trutek agreed to refund Jintec the license fee and deposit payment Trutek received from Jintec.

IX Annual Quantities – Minimum & Projected Targets and Unit Pricing/Terms:

(a) After product approval or freedom to sales is granted by Health Authorities, Jintec shall immediately, but no later than 10 calendar days, place a Purchase Order ("PO") for 250,000 units of 3.00 gm gel tubes. However, Trutek shall complete the reformation described in Clause VIII (d) at the timing of placing order.

(b) Trutek has agreed to extend, for due considerations of cooperation and executing Agreement with Jintec, a Preferred Customer pricing and offer a unit price of USD 3.54 for all single purchase orders of 100,000 units or more with single shipment and USD 3.19 for all single purchase orders of 250,000 units or more with (2) shipment for the term of this Agreement. The parties agree that minimum order quantity of each purchase order shall be over 100,000 units.

(c) In addition, to cooperate and extend assistance in Jintec marketing investment, Trutek has offered following additional discount for initial two (2) contract years. A contract year herein refers to one calendar year calculated from the date of initial commercial shipment.

i) 22.5% discount over its unit price of $3.19 i.e. a unit price of $2.47 for Purchase orders over 250,000
ii) 10.0% discount over the unit price of $3.54 i.e. a unit price of $3.18 for purchase orders over 100,000 units.

The parties have agreed that the above additional discount shall apply only for the first two years of the Agreement, and Not thereafter.

(c) This Agreement is subject to automatic renewal for following year, unless Jintec has a breach uncured for 30 days of notification and as long as the Contract Annual Minimum Quantity (1st year - 250,000 tubes, 2nd year – 500,000 tubes, 3rd year – 750,000 tubes, 4th year – 1,000,000 tubes, 5th year & onwards – 1,000,000 tubes) is achieved.

(d) All unit prices quoted are ex-factory NJ, USA. All sales are final. No return or credit except for damaged product. Damages must be reported within seven days of delivery. Normal delivery lead time, upon receipt of firm PO, will be 14 -18 weeks.

(e) Distributors and other customers will not repackage, re-tube, re-bottle, re-label, affix stickers or in any way modify the finished goods furnished in accordance with this Agreement except with the express written consent of Trutek.

(f) Trutek shall not be deemed in default or breach of this Agreement or any purchase order received from customers as a result of any delay in shipping orders caused by circumstances beyond Trutek's control such as, but not limited to, strikes, fires, accidents, lockouts, work stoppages or inability to procure supplies or materials.

X. Regulatory Obligations by Jintec:

(a) Jintec shall have the discretion of importation and marketing of NasalGuard products currently marketed and distributed in the USA as a General Purpose article for personal care use or any other class or classification to restrict the inhalation of airborne particles, when used as directed, from entering the nasal passages. Such particles include pollen, fine dust and dust mites, mold/spores and other airborne contaminants etc. Trutek claims there is no drug action or any active ingredient in the product. Such discretion for Regulatory Compliance by Jintec shall be exercised with an objective to achieve the Maximum Commercialization of the NasalGuard products in South Korea with the reasonably quickest time after launch.

(b) Jintec may launch the Product without registration, at its own risk and discretion, in the event it is not regulated by Health Authority. Instead, soon after the Product has been rolled out in the market, Jintec, at its own expense, may file the Product under medical device II according to ministry of food and drug safety (MFDS) guideline. For this purpose, Trutek has provided Jintec with any and all technical, commercial and regulatory information, data, including but not limited to descriptions of bench tests, labs, in vitro safety, ex vivo virucidal studies, clinical, analytical, microbial, and texture testing (tackiness) of all studies it has previously completed so far.

(c) Any additional work, publishing of peer review articles, testing and clinical studies e.g.; testing for efficacy on PM 2.5, similar, enhanced/different or combined clinical claims, or Indication for Use and marketing claims etc. as applicable to South Korea consumer environment for South Korea launch or any/all Regulatory approvals, as required, shall be at the sole expense and the responsibility of Jintec to launch and continue marketing of the products. Jintec shall prepare, review, and submit such filing documents for Trutek's review, consideration, and proof of filing and for Trutek's record on Trutek's behalf. Jintec shall, however, have and continue to have the rights to use of such approvals as long as this

Agreement with Trutek is valid. Upon termination of this Agreement, all such rights granted to Jintec shall cease to exist and any use, implied or explicit, by Jintec shall be a breach and violation of this Agreement.

XI. Infringements in South Korea:

(a) Jintec shall advise Trutek of any infringements in South Korea of Product trademarks, trade names, copyrights or designs or any imitations of any Products of which it becomes aware. Trutek shall take such immediate steps as are reasonably necessary to protect Trutek's rights, and Jintec shall assist and cooperate with Trutek in enforcing such rights. Jintec agrees not to contact the third party, not to make any demands or claims, not to institute any suit nor take any other action on account of such infringements or limitations without first obtaining the prior written permission of Trutek.

(b) With respect to all claims and suits, including suits in which Jintec is joined as a party; Trutek shall have the sole right to employ counsel of its choosing and to direct the handling of the litigation and any settlement thereof. Trutek shall bear all expenses connected with the foregoing, except that, if Jintec desires to retain its own counsel, it shall do so at its expense. Any recovery as a result of such actions shall be shared equally between Trutek and Jintec. In case a third party has alleged infringement in the Territory of trademarks, copyrights, patents or other intellectual property rights owned by such third-party, in relation to distributing the Products hereunder, Jintec shall inform Company of such claim or allegation and the parties shall take necessary action in cooperation, except where the subject matter is Jintec's trademark.

(c) If Trutek fails to dispute about such allegation with such party or if Jintec decides not to dispute about it, Jintec may terminate this Agreement without prejudice to all other rights claimable, or remedies obtainable from, Trutek hereunder for any and all of its loss and damages sustained thereby, except where the subject matter of the alleged infringement is Jintec's own trademark.

XII. **Payments:** All payment(s) to Trutek shall be made via wire transfer to Trutek's designated Bank Account, unless otherwise notified, at TD Bank, 50 West Main Street, Somerville NJ 08876, USA, Account No. 7855926817, Routing No. 031201360, along with Jintec's purchase order for Trutek to start production for subsequent shipment of the product. The payment terms shall be 30% with the P.O.; 60% upon proof of shipment provided by Jintec's freight forwarding company in the USA, and balance 10% within 10 calendar days upon arrival of shipment in South Korea. All shipments are final; subject to returns only due to deviation from proposed specifications and approved specimen samples of acceptance.

XIII. **Proposed Shipment Packing:** Trutek and Jintec will agree to specifications and quantities of bulk shipment by air or by sea, of filled tubes to Jintec.

XIV. **Non-Compete Clause:** During the term hereof of this Agreement and for five years (5) thereafter, both parties, its subsidiaries, affiliates, corporate parents and commonly controlled companies will not distribute, sell, market or promote any product which competes or is likely to compete with any of the Trutek's Products in the Territory.

XV. Warranties:

Trutek warrants that:

(a) It owns the Products and Documentation; and

(b) It is authorized to enter into this Agreement and does so without breaching any contract that it has with a third party.

Jintec warrants that:

(a) It is skilled and experienced at promoting, marketing and advertising products which are similar to the Products within the Territory; and

(b) It shall carry out all its obligations, and has sufficient resources (financial and otherwise) under this Agreement in a timely manner and using reasonable skill and care.

XVI. Dispute Resolution:

(a) If any disputes occur over the fulfillment of this Agreement, the parties shall try to resolve them amicably.

(b) If the parties cannot resolve the dispute amicably, then plaintiff shall file their complaint in the county where defendant resides.

The party that does not implement the award voluntarily shall be obligated to pay all the costs including but not limited to attorney's fees, legal expenses and costs related to recovery of damages, for the other party to implement the award.

(c) The laws that shall govern the dispute or resolution shall be the laws of the State of New Jersey, USA.

XVII. Assignment, Sub-contracting, Transfer or Termination of the Rights, Binding on Successor/Assign/Transferee:

(a) Trutek may assign/transfer its rights to a successor, assignee or transferee if the situation so requires. Such successor, assignee or transferee shall abide by the terms in this agreement.

(b) Jintec shall not assign, transfer, or deal in any way with any of its rights or obligations under this Agreement or sub-contract the performance of any of its obligations under this Agreement without the prior written approval of Trutek. Such approval not to be unreasonably withheld or delayed.

(c) This Agreement may terminate if either party has ceased operation or becomes insolvent or bankrupt, or when Jintec does not meet any of the requirements as set forth in this Agreement and fails to cure the same no later than 30 calendar days upon notification to do so. Failure to renew trademark or maintenance of Intellectual Property rights by Trutek does not automatically terminate its rights in this Agreement.

(d) In addition to all other rights and remedies which Trutek may have in law or in equity, Trutek may, at its option, terminate this Agreement by giving written notice of termination, in the event of (I) breach of this Agreement by Jintec, including a breach of the terms of payment or

the failure of Jintec to advance payments for goods which have been ordered and for which shipment has been prepared; (2) failure of Jintec to perform any obligations undertaken in this Agreement; (3) insolvency or bankruptcy of Jintec or (4) any transfer or assignment, or attempted transfer or assignment of this Agreement or any right or obligation hereunder or any sale or transfer of any interest in the ownership or control of Jintec without the prior written consent of Trutek.

XVIII. Third Party Rights:

A person who is not party to this Agreement shall have no rights under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this Agreement. This clause does not affect any right or remedy of any person, which exists or is available otherwise than pursuant to that Act.

XIX. **Validity and Entire Agreement**: If any provision in this agreement is invalid, the remaining provisions shall continue to be valid and effective.

This Agreement represents the parties' entire agreement with respect to the subject matter hereof and supersedes and replaces any prior agreement. or understanding (whether written or oral) with respect to the subject matter hereof. This Agreement may be waived, amended or supplemented only by an instrument in writing signed by the party against which such waiver, amendment or supplement is sought to be enforced.

XX. **Section Headings:** The headings in this Agreement are inserted only as a matter of convenience and for reference and in no way define, limit or describe the scope or intent of this Agreement.

By: _____

Name: Ashok Wahi

Title: President

Trutek Corp.

By: _____

Name: Peter Cho

Title: President

Jintec America Inc.

CONFIDENTIAL DISCLOSURE AGREEMENT

THIS Agreement is entered into by and between Ashok Wahi, President, Trutek Corp. or their designees (hereinafter the Principal) and Mr. Peter Cho as President, Jintec America Inc. 210, Sylvan Ave., #24, Englewood Cliffs, NJ 07632 and as an individual residing at 534A Hillside Avenue, Palisades Park, NJ 07650 as of March 4, 2019 (hereinafter the Disclosee).

WHEREAS, the Principal and the Disclosee wish to further discussions regarding NasalGuard® with special features, attributes and additional claims, Miracle Under-Eye™, NasalGuard® Unscented, NasalGuard® Allergie Block®, NasalGuard Cold & Flu Block®, NasalGuard® Multi Acting™, NasalGuard® Single Application Sachets, NasalGuard MF, NasalGuard Airborne Particle Blocker, NasalGuard Personal Air-Filter Gel, NasalGuard Particle Blocking Gel, Anti-Stat Enhanced Mask™, NasalGuard Wipes™, NasalGuard Allergie Wipes™, NasalGuard Cold & Flu Wipes™, Skin and Hair super conditioners, Truteks®Skin and Truteks® skin care products, electrostatically charged nasal multipurpose products, nasal application (anti-stat) diagnostic products and, associated Technologies and Methodologies, Patented and Pending Patent Applications, Chloraseptic Allergen Block and Little Allergies Allergen Block, Eisai Crystal Veil, Eisai Crystal Veil Cool, Nitto Nuru Mask, Nitto NasalGuard, including but not limited to nasal application product lines such as gels, pre-moistened products for e.g. applicators, swabs, wipes, etc., sticks, nasal sprays, nasal washes, surgical masks, multi-acting/integrated products, etc. and all other Trutek products (hereinafter the "project"); and

WHEREAS, in order to further such discussions, it will be necessary for the Principal to disclose the Disclosee certain data, samples and information relating to the project which it considers to be confidential and proprietary; and

WHEREAS, the Disclosee agrees to receive such information regarding the "project" in accordance with the terms and conditions contained herein and use it specifically and exclusively for the Principal.

NOW, THEREFORE, in consideration of the mutual benefits in furthering the interests of the parties the parties agree as follows:

1. As used herein, "Confidential Information" shall mean all data, sample information relating to the "project" hereafter disclosed by the Principal to the Disclosee except any documented information that is rightfully in Disclosee's possession prior to the date of this Agreement evidenced by pre-dated written reports and correspondence.

2. The Disclosee agrees that it will maintain all Confidential Information in strict Confidence and that it will not permit Confidential Information in its possession to be disclosed to any third party or used for any purpose not authorized by the Principal in writing.

3. Upon request by the Principal, the Disclosee will return all Confidential Information to The Principal and destroy or erase all additional copies and recordings thereof. Notwithstanding the foregoing, the obligations of confidentiality and non-use established herein shall continue in full force and effect for a period of 10 years from the date hereof.

4. The obligations contained in this Agreement shall extend to and be binding upon any employee or affiliate of the Disclosee, who has access to Confidential Information pursuant to this Agreement. The Disclosee shall obtain the agreement of those employees and affiliates who are granted access to the Confidential Information to comply with the terms hereof. Under no circumstances will the Disclosee attempt to profit from the project in any form other than through an agreement with the Principal.

5. All unique developments, Inventions and Improvements, patentable or not, as a result Disclosee's involvement with the "Project" shall belong to the Principal. The Principal shall have sole, complete and irrevocable rights to all such improvements, Inventions and Patents without any further verbal or written authorization from the Disclosee. The Disclosee's proprietary, patented or copyrighted information, data or processes will not be affected by this agreement.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives on date written above.

Ashok Wahi s/a
Ashok Wahi (The Principal)
President, Trutek Corp.

Witnessed by:

3/4/19
Peter Cho (The Disclosee)
President, Jintec America Inc.

3/4/19
Witnessed by:

TRUTEK CORP.
465 Somerville Road, Basking Ridge, NJ 07920 USA Tel: 908-685-1111

Jintec America, Inc.
210 Sylvan Avenue # 24
Englewood Cliffs, NJ 07632

May 13, 2019

Attn.: **Mr. Peter Cho, President Jintec America, Inc.**

Dear Mr. Cho,

This letter is to correct and seek your approval regarding the following minor typos in the Agreement dated May 12, 2019 signed by Trutek Corp. and Jintec America, Inc.

1. Section VIII on page 3 of 9 of the Agreement:
   Reformulation of NasalGuard Gel; **'relative'** government authorities is corrected to **"related"** government authorities.

2. Section IX on page 4 of 9 of the Agreement:
   Minimum & Projected Targets and Unit Pricing/Terms;
   - IX (a) Reformulation described in Clause VIII (d) at the **'timing'** of placing order, is corrected to reformulation described in Clause VIII (d) at the **"time"** of placing order.
   - Clarification:- IX (c) on page 4 of 9 of the agreement continues as IX (c) on page 5 of 9 of the agreement.

This letter is considered as part of the Agreement.

Truly Yours,

Ashok Wahi
Ashok Wahi
President
Trutek Corp.

Accepted by:

Peter Cho
Title: President
Jintec America, Inc.

EXHIBIT 3

November 6th Agreement
(China & Vietnam - Trutek/Jintec)

Agreement

For Importation, Marketing, Sales & Distribution of
Trutek's NasalGuard® Gel -Tube Product in Greater China and Vietnam

This Agreement is entered into on this 6th day of November, 2019 between Trutek Corp., a New Jersey (NJ) Corporation, with its registered office at 465 Somerville Road, Basking Ridge, NJ 07920, USA (hereafter "Trutek") and Jintec America, Inc. 210 Sylvan Avenue # 24, Englewood Cliffs, NJ 07632, USA (hereafter "Jintec")

WHEREAS, Trutek is the lawful and legal owner of the US registered trademarks of Truteks and NasalGuard for NasalGuard® (Year Round Topical) Gel - Tube Product (hereafter "Product") and desires to grant Jintec an exclusive license for Importation [in Primary Container i.e. filled & sealed tubes] for Secondary Packaging, Marketing (advertising & promotion), Sales, and Distribution of NasalGuard® products in Greater China area including Mainland China, Hong Kong, Macau, Taiwan, (hereinafter Greater China) and Vietnam; provided that Jintec obtains the necessary permits or approvals for the products from the concerned government authorities.

WHEREAS, Jintec, having conducted sufficient due diligence, desires to be licensed by Trutek to fulfill all obligations granted by Trutek under this Agreement;

WHEREAS, both parties have had the opportunity to seek independent legal counsel for this Agreement, have read and understood all the terms of the agreement, have signed this Agreement freely and voluntarily, without any duress or coercion, and have agreed to abide by the terms of this Agreement;

NOW, THEREFORE, in mutual benefits the parties agree as follows:

I. **Confidentiality**: Any data, documentation, information, literature or publications in any and all formats; and samples or materials submitted to Jintec by Trutek prior and during the Term of this Agreement shall be bound by the terms of the executed Confidential Disclosure Agreement executed on March 4, 2019 (Attachment I") for a minimum period of ten years upon termination of this Agreement.

II. **Trade Secrets, Trademarks, and Patent Protection:**

(a) Trutek does not grant and Jintec does not claim and will not claim any rights whatsoever with respect to Trutek's Trade Secrets and Intellectual Property (hereafter "IP"), and Jintec hereby acknowledges Trutek's exclusive right and title in the Territory and elsewhere to the Products and Trutek's Trade Secrets and Intellectual Property. The phrase "Trutek's Trade Secrets and Intellectual Property" refers to Trutek's trademarks, patents and patents-pending, goodwill, trade names, trade secrets, manufacturing and selling processes, knowhow and techniques, secret formulae, copyrights, designs, and other materials of any kind whatsoever employed in connection with the manufacture, assembly, packaging, offering for sale, advertisement, promotion and sale of the Products. In addition, Jintec shall not attempt to manufacture or

commission the manufacturing of the Trutek's product NasalGuard herein or any products, which shall be developed by Trutek in the future.

(b) Jintec shall not register any of Trutek's trademarks, trade names, designs or copyrights, or obtain any patents covering the Products in Greater China and Vietnam covered by this Agreement or anywhere else.

(c) Upon execution of this Agreement, Jintec may register Trutek's trademarks (similar or equivalent of Truteks and NasalGuard and others) in connection with the sales of the Products with the consent of Trutek, which will not be unreasonably withheld provided such trademarks are assigned to Trutek under the Clause II (d). Any such filing for trademark registration for launch of the Products shall be done no later than 30 days from the date of signing this Agreement by a qualified/accredited trademark attorney in Greater China and Vietnam retained and paid for by Jintec. Jintec is only permitted to use during the term of this Agreement the trademarks of the Product, in accordance with the provisions of this Agreement, and any and all use by Jintec of said trademark shall inure to the benefit of Trutek, and Jintec shall acquire no rights in said marks through such use.

(d) In the event that this Agreement is terminated, Jintec shall not use these trademarks on the Products, and Jintec shall assign and return all said trademarks to Trutek with Trutek's payment of registration fees and trademark attorney's fees, sincerely and diligently to be mutually negotiated by Trutek and Jintec.

III. **Initial Term:** The parties have agreed to an initial term of five years starting from the execution of this Agreement. This Agreement shall be automatically renewable unless a written notice to terminate is given at least 90 days prior to the expiration of the term by either party to the other. Such termination shall not, however, occur upon Trutek's initiation if Jintec continues to meet the 'minimum' sales requirement stipulated in Clause VIII (d) during the term of this Agreement, unless there's a breach by Jintec uncured for 30 days of notification by Trutek.

IV. **Distribution of Products:** The primary container (i.e. filled and sealed tubes) to be packaged in secondary packaging and distributed by Jintec shall include 3.00 gm NasalGuard gel in tubes, bulk-packed for cartoning and secondary packaging by Jintec for importation through commercial sales to consumers in and exclusively for Greater China and Vietnam.

V. **Exclusivity/Territory:** Trutek grants Jintec the license and distribution rights in "Greater China" and Vietnam as set forth above. No sales are permitted outside Greater China and Vietnam. Any violation of the 'sales territory' not reversed within 30 days from notification shall be a cause of the termination of this Agreement.

VI. **Use of Trutek's NasalGuard® Trademark and Intellectual Property Rights by Jintec:**

(a) Jintec shall use Trutek's and NasalGuard trademarks (Trutek's registered trademark) on the products & carton graphics and advertisement & promotional materials. Upon receipt of Trutek's prior approval, NasalGuard may be co-branded with Jintec's trademark/brand name as long as both brand names are indicated/publicized in substantially equivalent prominence and placements.

(b) Jintec shall be responsible to supply the design (graphic artwork & mechanical) of the Primary Container i.e.; tube, the secondary packaging including carton, labeling and regulatory compliance, packaging, through distribution subject to approval of all copies, ads, promotional materials explicitly, conspicuously and prominently indicating NasalGuard® trademark on all such materials. Jintec shall have an exclusive and automatic use of rights for the NasalGuard trademark during the entire term of its Agreement with Trutek. Jintec will respect the Intellectual Property Rights of Trutek Corp. and with due prominence indicate 'Created with NasalGuard Patented Technology' and some verbiage to that extent for Trutek Corp's "IP" rights on the product carton and all advertising and promotional materials.

VII. **License Fees:** Trutek grants Jintec an exclusive license for Importation [in Primary Container i.e. filled & sealed tubes] for Secondary Packaging, Marketing (advertising & promotion), Sales, and Distribution of NasalGuard® products in Greater China and Vietnam as long as this Agreement is valid. For this License, Jintec has agreed to pay Trutek a License Fee of USD300,000 in two installments of USD100,000 by November 30, 2019 and USD200,000 by December 20, 2019.

VIII. **Annual Quantities – Minimum & Projected Targets and Unit Pricing/Terms:**

(a) Jintec shall, no later than ~~December 30, 2019~~ January 30, 2020, place a Purchase Order ("PO") for 250,000 units at USD2.47 or 150,000 units at USD2.83 of 3.00 gm gel tubes for each SKU. The parties agree that the quantity of the 1st purchase order is based on one (single) SKU only.

(b) Trutek has agreed to extend, for due considerations of cooperation and executing Agreement with Jintec, a Preferred Customer pricing and offer a unit price of USD3.54 for all single purchase orders of 100,000 units for each SKU or more with single shipment and USD3.19 for all single purchase orders of 250,000 units for each SKU or more with (2) shipments for the term of this Agreement. The parties agree that minimum order quantity of each purchase order shall be over 100,000 units for each SKU.

(c) In addition, to cooperate and extend assistance in Jintec marketing investment, Trutek has offered following additional discount for initial two (2) contract years. A contract year herein refers to one calendar year calculated from the date of initial commercial shipment.

i) 22.5% discount over its unit price of USD3.19 i.e. a unit price of USD2.47 for Purchase orders over 250,000 units
ii) 10.0% discount over the unit price of USD3.54 i.e. a unit price of USD3.19 for purchase orders over 100,000 units.

The parties have agreed that the above additional discount shall apply only for the first two years of the Agreement, and Not thereafter.

(d) This Agreement is subject to automatic renewal for following year, unless Jintec has a breach uncured for 30 days of notification and as long as the Contract Annual Minimum Quantity (1st year - 350,000 units, 2nd year – 750,000 units, 3rd year – 1,250,000 units, 4th year & onwards – 2,000,000units per year,) is achieved.

(e) All unit prices quoted are ex-factory NJ, USA. All sales are final. No return or credit except for damaged product. Damages must be reported within seven days of delivery. Normal delivery lead time, upon receipt from approval of the tube graphics by Jintec, will be 14 -18 weeks.

(f) Distributors and other customers will not repackage, re-tube, re-bottle, re-label, affix stickers or in any way modify the finished goods furnished in accordance with this Agreement except with the express written consent of Trutek.

(g) Trutek shall not be deemed in default or breach of this Agreement or any purchase order received from customers as a result of any delay in shipping orders caused by circumstances beyond Trutek's control such as, but not limited to, strikes, fires, accidents, lockouts, work stoppages or inability to procure supplies or materials.

IX. Regulatory Obligations by Jintec:

(a) Jintec shall have the discretion of importation and marketing of NasalGuard products currently marketed and distributed in the USA as a General Purpose article for personal care use or any other class or classification to restrict the inhalation of airborne particles, when used as directed, from entering the nasal passages. Such particles include pollen, fine dust, yellow dust and dust mites, mold/spores and other airborne contaminants etc. Trutek claims there is no drug action or any active ingredient in the product. Such discretion for Regulatory Compliance by Jintec shall be exercised with an objective to achieve the Maximum Commercialization of the NasalGuard products in Greater China and Vietnam with the reasonably quickest time after launch.

(b) Jintec may launch the Product without registration, at its own risk and discretion, in the event it is not regulated by Health Authority. Instead, soon after the Product has been rolled out in the market, Jintec, at its own expense, may file the Product under medical device II according to ministry of food and drug safety (CFDA) guideline. For this purpose, Trutek has provided Jintec with any and all technical, commercial and regulatory information, data, including but not limited to descriptions of bench tests, labs, in vitro safety, ex vivo virucidal studies, clinical, analytical, microbial, and texture testing (tackiness) of all studies it has previously completed so far.

(c) Any additional work, publishing of peer review articles, testing and clinical studies e.g.; testing for efficacy on PM 2.5, similar, enhanced/different or combined clinical claims, or Indication for Use and marketing claims etc. as applicable to Greater China and Vietnam, consumer environment for Greater China and Vietnam launch or any/all Regulatory approvals, as required, shall be at the sole expense and the responsibility of Jintec to launch and continue marketing of the products. Jintec shall prepare, review, and submit such filing documents for Trutek's review, consideration, and proof of filing and for Trutek's record on Trutek's behalf. Jintec shall, however, have and continue to have the rights to use of such approvals as long as this Agreement with Trutek is valid. Upon termination of this Agreement, all such rights granted to Jintec shall cease to exist and any use, implied or explicit, by Jintec shall be a breach and violation of this Agreement.

X. Infringements in China:

(a) Jintec shall advise Trutek of any infringements in China of Product trademarks, trade names, copyrights or designs or any imitations of any Products of which it becomes aware. Trutek shall take such immediate steps as are reasonably necessary to protect Trutek's rights, and Jintec shall assist and cooperate with Trutek in enforcing such rights. Jintec agrees not to contact the third party, not to make any demands or claims, not to institute any suit nor take any other action on account of such infringements or limitations without first obtaining the prior written permission of Trutek.

(b) With respect to all claims and suits, including suits in which Jintec is joined as a party; Trutek shall have the sole right to employ counsel of its choosing and to direct the handling of the litigation and any settlement thereof. Trutek shall bear all expenses connected with the foregoing, except that, if Jintec desires to retain its own counsel, it shall do so at its expense. Any recovery as a result of such actions shall be shared equally between Trutek and Jintec. In case a third party has alleged infringement in the Territory of trademarks, copyrights, patents or other intellectual property rights owned by such third-party, in relation to distributing the Products hereunder, Jintec shall inform Company of such claim or allegation and the parties shall take necessary action in cooperation, except where the subject matter is Jintec's trademark.

(c) If Trutek fails to dispute about such allegation with such party or if Jintec decides not to dispute about it, Jintec may terminate this Agreement without prejudice to all other rights claimable, or remedies obtainable from, Trutek hereunder for any and all of its loss and damages sustained thereby, except where the subject matter of the alleged infringement is Jintec's own trademark.

XI. Payments: All payment(s) to Trutek shall be made via wire transfer to Trutek's designated Bank Account, unless otherwise notified, at TD Bank, 34 East Somerset Street, Raritan, NJ 08869, USA, Account No. 7855926817, Routing No. 031201360, along with Jintec's purchase order for Trutek to start production for subsequent shipment of the product. The payment terms shall be 30% with the P.O.; 60% upon proof of shipment provided by Jintec's freight forwarding company in the USA, and balance 10% within 10 calendar days upon arrival of shipment at the designated warehouse in Greater China. All shipments are final; subject to returns only due to deviation from proposed specifications and approved specimen samples of acceptance.

XII. Proposed Shipment Packing: Trutek and Jintec will agree to specifications and quantities of bulk shipment by air or by sea, of filled tubes to Jintec.

XIII. Non-Compete Clause: During the term hereof of this Agreement and for five years (5) thereafter, Jintec, its subsidiaries, affiliates, corporate parents and commonly controlled companies will not distribute, sell, market or promote any product which competes or is likely to compete with any of the Trutek's Products in the Territory.

XIV. Warranties:

Trutek warrants that:

(a) It owns the Products and Documentation; and

(b) It is authorized to enter into this Agreement and does so without breaching any contract that it has with a third party.

Jintec warrants that:

(a) It is skilled and experienced at promoting, marketing and advertising products which are similar to the Products within Greater China and Vietnam; and

(b) It shall carry out all its obligations, and has sufficient resources (financial and otherwise) under this Agreement in a timely manner and using reasonable skill and care.

XV. Dispute Resolution:

(a) If any disputes occur over the fulfillment of this Agreement, the parties shall try to resolve them amicably.

(b) If the parties cannot resolve the dispute amicably, then plaintiff shall file their complaint in the county where defendant resides.

The party that does not implement the award voluntarily shall be obligated to pay all the costs including but not limited to attorney's fees, legal expenses and costs related to recovery of damages, for the other party to implement the award.

(c) The laws that shall govern the dispute or resolution shall be the laws of the State of New Jersey, USA.

XVI. Assignment, Sub-contracting, Transfer or Termination of the Rights, Binding on Successor/Assign/Transferee:

(a) Trutek may assign/transfer its rights to a successor, assignee or transferee if the situation so requires. Such successor, assignee or transferee shall abide by the terms in this agreement.

(b) Jintec shall not assign, transfer, or deal in any way with any of its rights or obligations under this Agreement or sub-contract the performance of any of its obligations under this Agreement without the prior written approval of Trutek. Such approval not to be unreasonably withheld or delayed.

(c) This Agreement may terminate if either party has ceased operation or becomes insolvent or bankrupt, or when Jintec does not meet any of the requirements as set forth in this Agreement and fails to cure the same no later than 30 calendar days upon notification to do so. Failure to renew trademark or maintenance of Intellectual Property rights by Trutek does not automatically terminate its rights in this Agreement.

(d) In addition to all other rights and remedies which Trutek may have in law or in equity, Trutek may, at its option, terminate this Agreement by giving written notice of termination, in the event of (l) breach of this Agreement by Jintec, including a breach of the terms of payment or the failure of Jintec to advance payments for goods which have been ordered and for which shipment has been prepared; (2) failure of Jintec to perform any obligations undertaken in this Agreement; (3) insolvency or bankruptcy of Jintec or (4) any transfer or assignment, or attempted transfer or assignment of this Agreement or any right or obligation hereunder or any sale or transfer of any interest in the ownership or control of Jintec without the prior written consent of Trutek.

XVII. Third Party Rights:

A person who is not party to this Agreement shall have no rights under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this Agreement. This clause does not affect any right or remedy of any person, which exists or is available otherwise than pursuant to that Act.

XVIII. Validity and Entire Agreement: If any provision in this agreement is invalid, the remaining provisions shall continue to be valid and effective.

This Agreement represents the parties' entire agreement with respect to the subject matter hereof and supersedes and replaces any prior agreement or understanding (whether written or oral) with respect to the subject matter hereof. This Agreement may be waived, amended or supplemented only by an instrument in writing signed by the party against which such waiver, amendment or supplement is sought to be enforced.

XIX. Section Headings: The headings in this Agreement are inserted only as a matter of convenience and for reference and in no way define, limit or describe the scope or intent of this Agreement.

By: _____

Name: Ashok Wahi

Title: President

Trutek Corp.

By: _____

Name: Peter Cho

Title: President

Jintec America Inc.

CONFIDENTIAL DISCLOSURE AGREEMENT

THIS Agreement is entered into by and between Ashok Wahi, President, Trutek Corp. or their designees (hereinafter the Principal) and Mr. Peter Cho as President, Jintec America Inc. 210, Sylvan Ave., #24, Englewood Cliffs, NJ 07632 and as an individual residing at 534A Hillside Avenue, Palisades Park, NJ 07650 as of March 4, 2019 (hereinafter the Disclosee).

WHEREAS, the Principal and the Disclosee wish to further discussions regarding NasalGuard® with special features, attributes and additional claims. Miracle Under-Eye™, NasalGuard® Unscented, NasalGuard® Allergie Block®, NasalGuard Cold & Flu Block®, NasalGuard® Multi Acting™, NasalGuard® Single Application Sachets, NasalGuard MF, NasalGuard Airborne Particle Blocker, NasalGuard Personal Air-Filter Gel, NasalGuard Particle Blocking Gel, Anti-Stat Enhanced Mask™, NasalGuard Wipes™, NasalGuard Allergie Wipes™, NasalGuard Cold & Flu Wipes™, Skin and Hair super conditioners, Truteks®Skin and Truteks® skin care products, electrostatically charged nasal multipurpose products, nasal application (anti-stat) diagnostic products and, associated Technologies and Methodologies, Patented and Pending Patent Applications, Chloraseptic Allergen Block and Little Allergies Allergen Block, Eisai Crystal Veil, Eisai Crystal Veil Cool, Nitto Nuru Mask, Nitto NasalGuard, including but not limited to nasal application product lines such as gels, pre-moistened products for e.g. applicators, swabs, wipes, etc., sticks, nasal sprays, nasal washes, surgical masks, multi-acting/integrated products, etc. and all other Trutek products (hereinafter the "project"): and

WHEREAS, in order to further such discussions, it will be necessary for the Principal to disclose the Disclosee certain data, samples and information relating to the project which it considers to be confidential and proprietary; and

WHEREAS, the Disclosee agrees to receive such information regarding the "project" in accordance with the terms and conditions contained herein and use it specifically and exclusively for the Principal.

NOW, THEREFORE, in consideration of the mutual benefits in furthering the interests of the parties the parties agree as follows:

1. As used herein, "Confidential Information" shall mean all data, sample information relating to the "project" hereafter disclosed by the Principal to the Disclosee except any documented information that is rightfully in Disclosee's possession prior to the date of this Agreement evidenced by pre-dated written reports and correspondence.

2. The Disclosee agrees that it will maintain all Confidential Information in strict Confidence and that it will not permit Confidential Information in its possession to be disclosed to any third party or used for any purpose not authorized by the Principal in writing.

3. Upon request by the Principal, the Disclosee will return all Confidential Information to The Principal and destroy or erase all additional copies and recordings thereof. Notwithstanding the foregoing, the obligations of confidentiality and non-use established herein shall continue in full force and effect for a period of 10 years from the date hereof.

4. The obligations contained in this Agreement shall extend to and be binding upon any employee or affiliate of the Disclosee, who has access to Confidential Information pursuant to this Agreement. The Disclosee shall obtain the agreement of those employees and affiliates who are granted access to the Confidential Information to comply with the terms hereof. Under no circumstances will the Disclosee attempt to profit from the project in any form other than through an agreement with the Principal.

5. All unique developments, inventions and improvements, patentable or not, as a result Disclosee's involvement with the "Project" shall belong to the Principal. The Principal shall have sole, complete and irrevocable rights to all such improvements, inventions and Patents without any further verbal or written authorization from the Disclosee. The Disclosee's proprietary, patented or copyrighted information, data or processes will not be affected by this agreement.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives on date written above.

Ashok Wahi (The Principal)
President, Trutek Corp.

Witnessed by:

3/4/19

Peter Cho (The Disclosee)
President, Jintec America Inc.

3/4/19

Witnessed by:

EXHIBIT 4

U.S. Patent 8,163,802
(The '802 Patent)

US008163802B2

(12) **United States Patent**
Wahi

(10) **Patent No.: US 8,163,802 B2**
(45) **Date of Patent: Apr. 24, 2012**

(54) **ELECTROSTATICALLY CHARGED MULTI-ACTING NASAL APPLICATION, PRODUCT, AND METHOD**

(75) Inventor: **Ashok Wahi**, Hillsborough, NJ (US)

(73) Assignee: **Trutek Corp.**, Hillsborough, NJ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 316 days.

(21) Appl. No.: **12/467,271**

(22) Filed: **May 16, 2009**

(65) **Prior Publication Data**

US 2010/0004337 A1 Jan. 7, 2010

Related U.S. Application Data

(60) Provisional application No. 61/085,855, filed on Aug. 3, 2008, provisional application No. 61/078,478, filed on Jul. 7, 2008.

(51) **Int. Cl.**
A61K 31/198 (2006.01)
A61K 31/14 (2006.01)

(52) **U.S. Cl.** **514/564**; 514/643

(58) **Field of Classification Search** 514/564, 514/643; 128/206.11
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

1,071,015	A	8/1913	Adler
2,237,954	A	4/1941	Wilson
2,433,565	A	12/1947	Korman
2,751,906	A	10/1953	Irvine
2,777,442	A	1/1957	Zelano
3,145,711	A	8/1964	Beber
3,513,839	A	5/1970	Vacante
4,030,491	A	6/1977	Mattila
4,052,983	A	10/1977	Bovender
4,267,831	A	5/1981	Aguilar
4,401,117	A	8/1983	Gershuny
4,789,504	A	12/1988	Ohmori et al.
4,874,659	A	10/1989	Ando et al.
5,468,488	A	11/1995	Wahi
5,674,481	A	10/1997	Wahi
6,844,005	B2	1/2005	Wahi
2003/0223934	A1	12/2003	Wahi

Primary Examiner — Raymond Henley, III
(74) *Attorney, Agent, or Firm* — Stanley H. Kremen

(57) **ABSTRACT**

A product to reduce and method of reducing the risk of inhalation of harmful substances by applying a formulation composition to a substrate or the skin in close proximity of one or more nostrils. This formulation, when applied creates an electrostatic field having a charge. The electrostatic field attracts airborne particulates of opposite charge to the substrate that are in close proximity to the substrate close to the skin and a biocidic agent renders microorganisms coming in contact the substrate or skin less harmful.

23 Claims, No Drawings

ELECTROSTATICALLY CHARGED MULTI-ACTING NASAL APPLICATION, PRODUCT, AND METHOD

CROSS REFERENCE TO RELATED APPLICATIONS

a) The Present application is the non-provisional counterpart of my pending U.S. Provisional Patent Application Ser. No. 61/085,555 (the '555 application) filed on Aug. 3, 2008 which is incorporated by reference in its entirety herein. The Present application claims the benefit of and priority to said '555 application.

b) The Present application is also the non-provisional counterpart of my pending U.S. Provisional Patent Application Ser. No. 61/078,478 (the '478 application) filed on Jul. 7, 2008 which is incorporated by reference in its entirety herein. The Present application claims the benefit of and priority to said '478 application.

c) The Present application is likewise related to my prior U.S. Provisional Patent Application Ser. No. 60/570,103 (the '103 application) filed on May 12, 2004 (now expired), and which is incorporated by reference in its entirety herein. The '478 application provides a virtually identical disclosure to the '103 application.

d) Furthermore, the Present application is related to my pending U.S. Provisional Application Ser. No. 61/078,472 filed on Jul. 7, 2008, which is incorporated by reference in its entirety herein.

e) The Present application is also related to my prior U.S. Provisional Patent Application Ser. No. 60/598,462 filed on Aug. 3, 2004 (now expired), and which is incorporated by reference in its entirety herein.

f) The Present application is additionally related to my U.S. Pat. No. 5,468,488, entitled "ELECTROSTATICALLY CHARGED NASAL APPLICATION PRODUCT AND METHOD" issued on Nov. 21, 1995. This patent is incorporated by reference in its entirety herein.

g) The Present application is further related to my U.S. Pat. No. 5,674,481, entitled "ELECTROSTATICALLY CHARGED NASAL TOPICAL APPLICATION PRODUCT" issued on Oct. 7, 1997. This patent is incorporated by reference in its entirety herein.

h) The Present application is moreover related to my U.S. Pat. No. 6,844,005 entitled "ELECTROSTATICALLY CHARGED NASAL APPLICATION PRODUCT WITH INCREASED STRENGTH" issued on Jan. 18, 2005. This patent is incorporated by reference in its entirety herein.

i) Finally, this application is furthermore related to US Non-Provisional Utility patent application Ser. No. 10/082,978 entitled "ELECTROSTATICALLY CHARGED NASAL APPLICATION PRODUCT WITH INCREASED STRENGTH" filed on Feb. 25, 2002. This patent application is incorporated by reference in its entirety herein.

FIELD OF THE INVENTION

The Present Invention relates to the field of protective compositions against assault by various irritants and noxious substances as well as against assault by assorted microorganisms that typically gain entry into the body through the airway and/or nasal mucosa. The Present Invention also relates to anti-viral, anti-bacterial, and anti-microbial products and methods that involve the use of products heretofore developed for restricting the flow of airborne contaminants into the nasal passages by creating an electrostatic field in an area near about the nasal passages. This reduced the inflow of airborne contaminants to the nasal passages by capturing the contaminants and keeping them from entering the body. In the present invention, these electrostatically charged nasal application products capture and hold the contaminants including viruses, bacteria, and other harmful microorganisms or toxic particulates, inactivate them dermally outside the body and render them harmless.

BACKGROUND OF THE INVENTION

The nasal passages and nasal mucosa serve as body entry points for a wide variety of noxious and toxic substances. The body's immune system responds with certain relatively harmless irritants to the nasal passages and airways with reflex responses such as coughing and sneezing. This merely reintroduces the irritants into the environment. However, when the irritant comprises microorganisms, especially those that reproduce within the body and that are transmitted by coughing and sneezing, others may become infected. When a person feels a cough or a sneeze coming on, he merely covers his nose and mouth. However, if that person is contagious, this action does little to prevent others from also becoming infected. Furthermore, the use of a tissue or handkerchief for this purpose is extremely inefficient. This limits the protection of an individual from becoming infected or infecting others.

Other means of dealing with preventing inhalation of harmful or irritating substances or of infections agents include wearing facemasks to filter out these irritants. An example of this is the simple dust mask, typically found in the hardware store or medical supply store. However, even these are inadequate and inefficient. In many localities, during flu season, one can see a large number of people wearing these dust masks in public places. The dust masks are now known to be ineffective. Another example of this preventative method is the gas mask, which is more efficient than the dust mask. Yet, even gas masks are not highly efficient with respect to microscopic and sub-microscopic microorganisms. Furthermore, they are extremely cumbersome and cannot generally be used during normal day-to-day activities.

Patents such as U.S. Pat. No. 6,844,005 describe electrostatically charged compositions that may be applied externally in the vicinity of the nostril and attract oppositely charged materials that would otherwise be inhaled. However, those compositions simply create an electrostatic field that helps to filter out oppositely charged materials. While this action may offer suitable protection against particles that are inhaled passively, they suffer from the fact that they cannot completely deal with particulates that have their own internal means of overcoming the electrostatic forces, such as microorganisms that are motile within the air stream. Furthermore, actions by the person having those electrostatic compositions in the vicinity of the nostrils can sufficiently displace the offending particles or organisms, especially in such instances as blowing or wiping the nose, so that particles that were held captive by the former compositions could become dislodged, again set free, and be inhaled.

OBJECTS OF THE INVENTION

It is therefore an object of the invention to provide a composition that can be readily applied to the exterior region around the nostril and/or slightly inside the edge of the nostril or near the vicinity of the source of release with method and compositions capable of capturing particulates and microorganisms.

It is another object of the invention to have the capability to hold it for a duration from being dislodged in to the air stream again.

It is a further object of the invention to provide a composition that can be applied near the vicinity of the source of release or to the area around the exterior of and/or slightly inside the edge of the nostril that will inactivate, kill, or render harmless a microorganism, which has been captured and held by the composition.

It is yet another object of the invention to provide a composition that can be applied to a filter substrate for improving the substrates ability to trap and hold particulates and microorganisms and to simultaneously inactivate, kill, or render harmless the microorganisms so trapped. Such filter substrate could be placed in the close proximity of the skin near the path of inhalation, near the source of release of such particulates while the inhaler is at a distance or both.

It is still another object of the invention to provide a method of prophylactically preventing or of substantially reducing the risk of infection by an infectious agent without the utilization of ingested antiviral and/or antibacterial agents.

Yet other objects of the invention will be apparent to those of ordinary skill once having benefit of the instant disclosure. In all of the foregoing objects, the deficiencies of the previously mentioned prior art are overcome by the teachings of this invention.

SUMMARY OF THE INVENTION

These and other objects of the invention are unexpectedly achieved by an electrostatically charged composition having at least one polymeric quaternary compound in an aqueous or non-aqueous based formulation, which when applied to a surface, creates an electrostatic field such that oppositely charged airborne particulates (including microorganisms) in the vicinity of the surface are electrostatically trapped, held thereto and one or more of the microorganisms so captured is neutralized, killed, inactivated, and rendered harmless.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to anti-microorganism, anti-viral/anti-bacterial products and methods that involve the use of products that restrict the flow of airborne contaminants into the nasal passages by creating an electrostatic field in an area near about the nasal passages. Additionally, in the present invention, these electrostatically charged nasal application products are used to hold the contaminants including micro-organisms, viruses, bacteria, and other harmful or toxic particulate outside the body and render them harmless.

Emergencies of Anthrax lead to the concept of avoidance of inhaling airborne microscopic and sub-microscopic contaminants. It is the intention of the Present Invention to filter and render harmless materials such as anthrax spores, human corona virus, smallpox virus, influenza virus, avian flu virus, swine flu virus, rhino virus, and other biological or chemical elements/toxins/irritants, and the like, prior to their entering the nasal passages.

Airborne microorganisms are a major cause of respiratory ailments in humans, causing allergies, asthma, and pathogenic infections of the respiratory tract. Airborne fungal spores are also important agents that spread diseases. Respiratory diseases cause many fatalities and are a cause of great concern. During a sneeze, millions of tiny droplets of water and mucus are expelled at a high velocity. The droplets contain viral particles and/or bacteria. This is a means of transmission of several diseases by inhaled airborne particles as follows:

VIRAL DISEASES (virus type in brackets)	BACTERIAL DISEASES (bacterial name in brackets)
Chickenpox (Varicella)	Whooping cough (*Bordetella pertussis*)
Flu (Influenza)	Meningitis (*Neisseria* species)
Measles (Rubeola)	Diphtheria (*Corynebacterium diphtheriae*)
German measles (Rubella)	Pneumonia (*Mycoplasma pneumoniae*, *Streptococcus* species)
Mumps (Mumps)	Tuberculosis (*Mycobacterium tuberculosis*)
Smallpox (Variola)	Anthrax (*Anthracsis* bacterium)
SARS (Human Corona)	

Diseases caused by environmental particulates include, but are not limited to the following:

ENVIRONMENTAL PARTICULATE DISEASES	SOURCE
Psittacosis (*Chlamydia psittaci*)	Dried, powdery droppings from infected birds (parrots, pigeons, etc.)
Legionnaire's disease (*Legionella pneumophila*)	Droplets from air-conditioning systems, water storage tanks, etc., where the bacterium grows.
Acute allergic alveolitis (various fungal and actinomycete spores)	Fungal or actinomycete spores from decomposing organic matter (composts, grain stores, hay, etc.)
Aspergillosis (*Aspergillus fumigatus*, *A. flavus*, *A. niger*)	Fungal spores inhaled from decomposing organic matter.
Histoplasmosis (*Histoplasma capsulatum*)	Spores of the fungus, in old, weathered bat or bird droppings.
Coccidioidomycosis (*Coccidioides immitis*)	Spores in air-blown dust in desert regions (Central, South and North America) where the fungus grows in the soil.

To accomplish the present invention, a formulation having at least one polyquaternary ammonium compound is prepared, such compounds, alone or together capable of creating an electrostatic field on and around a surface to which it is applied, including surfaces such as skin, textile (woven and non-woven), and hard surfaces, such as floors, walls, wood, metal, plastic, etc. The formulation is generally aqueous based, but may include non-aqueous solvents used which are compatible with the other formulation components and the application surface to which it is applied. Preferably, the formulation is an aqueous formulation. In addition to the polyquaternary ammonium compound, the composition includes at least. Furthermore, the composition may contain, but is not required to contain various thickeners, gellants, fragrances, colorants, emollients, humectants, and generally other suitable components that are compatible with the end use application and the other components of the formulations. Thus, a composition of the invention that is intended to be applied to a filter substrate that is perhaps used as a mask with an additional liner between a user and the filter substrate may utilize materials that would not be compatible with direct contact with skin, although it is preferable that all of the components are compatible with direct application to the skin as a means of limiting reaction due to inadvertent contact between the composition and the skin.

A formulation of the invention comprises:

water,

at least one quaternary thickener,

a preservative,
a conditioner,
an emulsifier,
a biocidic agent, and
a neutralizing agent added to adjust and achieve a pH in the range of 5.0 to 6.8.

It may further comprise without limitation a combination of the following:

a surfactant,
a thickener,
an emollient,
a humectant, and
a binder.

In an exemplary embodiment of such a formulation, a quaternary thickener may comprise without limitation, at least one of the following:

Polyquaternium-10
Polyquaternium-22
Polyquaternium-67
Polyquaternium-70
Polyquaternium-72
Polyquaternium-88
Cocodimonium Hydroxypropyl Hydrolyzed Keratin
Hydroxypropyltrimonium Wheat Protein

Benzalkonium Chloride may also serve the same function, but it is also a cationic agent as well as a biocide. Another biocide that may be used is Lysine HCL.

In an exemplary embodiment of such a formulation, an emulsifier may comprise without limitation, at least one of the following:

Cetyl Alcohol (which can also serve as a thickener)
Cetearyl Alcohol
Glyceryl Stearate
Ceteareth-20
PEG-40 Stearate
Dicetyl Phosphate
Ceteth-10 Phosphate

In an exemplary embodiment of such a formulation, the emollient may be Isocetyl Behenate without limitation. The thickener may be Cetyl Alcohol or Stearyl Alcohol without limitation.

In an exemplary embodiment of such a formulation, a preservative may comprise without limitation, at least one of the following:

Phenoxyethanol;
Methylparaben;
Butylparaben;
Ethylparaben;
Propylparaben;
Isobutylparaben.

Examples of typical formulations found to be effective appear in the ten tables that follow. Percentages are given by weight.

TABLE 1

Ingredient	Percent Range	Function
Water	62%-80%	Solvent, Moisturizer
Gluconolactone, Sodium Benzoate	1%	Preservative
Lysine HCL	1%	Conditioner
Polyquaternium - 67	3%-6%	Conditioner
Octoxynol - 9	2%-5%	Surfactant
Polyquaternium - 72	6%-10%	Conditioner
Polyquaternium - 70	0.5%-1%	Conditioner
Dipropylene Glycol Isocetyl Behenate	4%-6%	Emollient
Stearyl Alcohol	1%-3%	Thickener
Cetyl Alcohol	0.25%-1%	Thickener
Ceteareth - 20, PEG - 40 Stearate, Cetearyl Alcohol	1%-2%	Emulsifier
Water, Hydrolyzed Algin	0.5%-1.5%	Conditioner
Hydrolized Soy Protein	0.25%-1%	Conditioner

TABLE 2

Ingredient	Percent Range	Function
Water	72%-88%	Solvent, Moisturizer
Phenoxyethanol Methylparaben, Propylparaben, Butylparaben, Ethylparaben, Isobutylparaben	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Polyquaternium - 67	3%-6%	Conditioner, Quaternary
Nonoxynol - 10	2%-4%	Surfactant
Cocodimonium Hydroxypropyl Hydrolyzed Keratin	0.5%-2%	Conditioner, Quaternary
Polyquaternium - 72	0.5%-2%	Conditioner, Quaternary
Polyquaternium - 88	1%-4%	Conditioner, Quaternary
Cetearyl Alcohol, Glyceryl Stearate Emulsifier, PEG - 40 Stearate, Ceteareth - 20	1%-4%	Emulsifier
Cetearyl Alcohol, Dicetyl Phosphate, Ceteth - 10 Phosphate	0.5%	Emulsifier
Benzalkonium Chloride	0.25%-1%	Cationic, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	0.01%-0.05%	Neutralizing Agent

TABLE 3

Ingredient	Percent Range	Function
Water	67%-87%	Solvent, Moisturizer
Phenoxyethanol, Methylparaben, Propylparaben, Butylparaben, Ethylparaben, Isobutylparaben	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Polyquaternium - 67	3%-7%	Conditioner, Quaternary
Polyquaternium - 72	3%-7%	Conditioner, Quaternary
Cocodimonium Hydroxypropyl Hydrolized Keratin	1%-4%	Conditioner, Quaternary
Polyquaternium - 88	1%-4%	Conditioner, Quaternary
Cetyl Alcohol	1.5%-2.5%	Thickener
Cetearyl Alcohol, Glyceryl PEG - 40 Stearate, Ceteareth - 20	1%-4%	Emulsifier
Benzalkonium Chloride	0.25%-1%	Cationic, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	.025%-.075%	Neutralizing Agent

TABLE 4

Ingredient	Percent Range	Function
Water	71%-83%	Solvent, Moisturizer
Phenoxyethanol, Methylparaben, Propylparaben, Butylparaben, Ethylparaben, Isobutylparaben	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Polyquaternium - 67	4%-6%	Conditioner, Quaternary
Polyquaternium - 72	4%-6%	Conditioner, Quaternary
Cocodimonium Hydroxypropyl Hydrolyzed Keratin	2%-4%	Conditioner, Quaternary
Polyquaternum - 88	1%-3%	Conditioner, Quaternary
Cetyl Alcohol	2%	Thickener
Cetearyl Alcohol, Glyceryl Stearate, PEG - 40 Stearate, Ceteareth - 20	1%-3.5%	Emulsifier
Benzalkonium Chloride	0.25%-1%	Cationic, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	.025%-.075%	Neutralizing Agent

TABLE 5

Ingredient	Percent Range	Function
Water	73%-85%	Solvent, Moisturizer
Phenoxyethanol, Methylparaben, Propylparaben, Butylparaben, Ethylparaben, Isobutylparaben	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Polyquaternium - 67	2%-3%	Conditioner, Quaternary
Polyquaternium - 72	4%-6%	Conditioner, Quaternary
Cocodimonium Hydroxypropyl Hydrolyzed Keratin	2%-4%	Conditioner, Quaternary
Polyquaternium - 88	1%-3%	Conditioner, Quaternary
Cetyl Alcohol	2%	Thickener
Cetearyl Alcohol, Glyceryl Stearate, PEG - 40 Stearate, Ceteareth - 20	1%-3%	Emulsifier
Benzalkonium Chloride	0.25%-1%	Cationic, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	0.05%-0.75%	Neutralizing Agent

TABLE 6

Ingredient	Percent Range	Function
Water	69%-85%	Solvent, Moisturizer
Phenoxyethanol, Methylparaben, Propylparaben, Butylparaben, Ethylparaben, Isobutylparaben,	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Polyquaternium - 10	0.25%-0.85%	Conditioner, Quaternary
Polyquaternium - 67	1.5%-3.5%	Conditioner, Quaternary
Polyquaternium - 72	4%-6%	Conditioner, Quaternary
Cetyl Alcohol	1%-3%	Thickener
Cocodimonium Hydroxypropyl Hydrolyzed Keratin	2%-4%	Conditioner, Quaternary
Polyquaternium - 88	1%-3%	Conditioner, Quaternary
Polyquaternium - 22	1%-3%	Conditioner, Quaternary
Cetearyl Alcohol, Glyceryl Stearate, PEG - 40 Stearate, Ceteareth - 20	1%-3%	Emulsifier
Benzalkonium Chloride	0.25%-1%	Conditioner, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	0.05%-0.75%	Neutralizing Agent

TABLE 7

Ingredient	Percent Range	Function
Water	67%-86%	Solvent, Moisturizer
Phenoxyethanol, Methylparaben, Butylparaben, Ethylparaben, Isobutylparaben	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Polyquaternium - 10	1%-4%	Conditioner, Quaternary
Polyquaternium - 67	1%-4%	Conditioner, Quaternary
Polyquaternium - 72	0.5%-1.5%	Conditioner, Quaternary
Cocodimonium Hydroxypropyl Hydrolized Keratin	0.5%-1.5%	Conditioner, Quaternary
Microcare Quat CTC 30	1%-3%	Conditioner, Quaternary
Polyquaternium - 88	1%-3%	Conditioner, Quaternary
Polyquaternium - 22	1%-3%	Conditioner, Quaternary
Cetyl Alcohol	3%-5%	Thickener
Cetearyl Alcohol, Glyceryl Stearate, PEG - 40 Stearate, Ceteareth - 20	2%-3%	Emulsifier
Benzalkonium Chloride	0.25%-1%	Conditioner, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	0.05%-0.1%	Neutralizing Agent

TABLE 8

Ingredient	Percent Range	Function
Water	58%-74%	Solvent, Moisturizer
Phenoxyethanol, Methylparaben, Propylparaben, Butylparaben, Ethylparaben, Isobutylparaben	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Glycerin	10%	Humectant
Glyceryl Acetate/Acrylic Acid Copolymer	1%	Conditioner, Humectant
Polyquaternium - 10	1%-4%	Conditioner, Quaternary
Polyquaternium - 67	1%-3%	Conditioner, Quaternary
Polyquaternium - 72	0.5%-1.5%	Conditioner, Quaternary
Cocodimonium Hydroxypropyl Hydrolyzed Keratin	0.5%-1.5%	Conditioner, Quaternary
Cetrimonium Chloride	1%-3%	Conditioner, Quaternary
Polyquaternium - 88	1%-3%	Conditioner, Quaternary
Polyquaternium - 22	1%-3%	Conditioner, Quaternary
Cetyl Alcohol	4%	Thickener
Cetearyl Alcohol, Glyceryl Stearate, PEG - 40 Stearate, Ceteareth - 20	2%-3%	Emulsifier
Polybutene	4%	Binder
Benzalkonium Chloride	0.25%-1%	Conditioner, Quaternary, Biocide

TABLE 8-continued

Ingredient	Percent Range	Function
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	.0.05%-0.1%	Neutralizing Agent

TABLE 9

Ingredient	Percent Range	Function
Water	54%-73%	Solvent, Moisturizer
Phenoxyethanol, Methylparaben, Propylparaben, Butylparaben, Ethylparaben, Isobutylparaben	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Glycerin	8%	Humectant
Glyceryl Acetate/Acrylic Acid Copolymer	1%	Conditioner, Humectant
Polyquaternium - 10	1%-4%	Conditioner, Quaternary
Polyquaternium - 67	1%-4%	Conditioner, Quaternary
Polyquaternium - 72	0.5%-2%	Conditioner, Quaternary
Cocodimonium Hydroxypropyl Hydrolyzed Keratin	0.5%-2%	Conditioner, Quaternary
Cetrimonium Chloride	1%-3%	Conditioner, Quaternary
Polyquaternium - 88	1%-3%	Conditioner, Quaternary
Polyquaternium - 22	1%-3%	Conditioner, Quaternary
Cetyl Alcohol	4%	Thickener
Cetearyl Alcohol, Glyceryl Stearate, PEG - 40 Stearate, Ceteareth - 20	2%-3%	Emulsifier
Polybutene	3%-4%	Binder
Benzalkonium Chloride	0.25%-1%	Conditioner, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	0.05%-0.1%	Neutralizing Agent

TABLE 10

Ingredient	Percent Range	Function
Water	52%-71%	Solvent, Moisturizer
Phenoxyethanol, Methylparaben, Propylparaben, Butylparaben, Ethylparaben, Isobutylparaben	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Glycerin	9%	Humectant
Glyceryl Acetate/Acrylic Acid Copolymer	1%	Conditioner, Humectant
Polyquaternium - 10	1%-3.5%	Conditioner, Quaternary
Polyquaternium - 67	1%-3%	Conditioner, Quaternary
Polyquaternium - 72	0.5%-2%	Conditioner, Quaternary
Cocodimonium Hydroxypropyl Hydrolyzed Keratin	0.5%-2%	Conditioner, Quaternary
Cetrimonium Chloride	1%-3%	Conditioner, Quaternary
Polyquaternium - 88	1%-3%	Conditioner, Quaternary
Polyquaternium - 22	1%-3%	Conditioner, Quaternary
Cetyl Alcohol	4%	Thickener
Cetearyl Alcohol, Glyceryl Stearate, PEG - 40 Stearate, Ceteareth - 20	1%-4%	Emulsifier
Polybutene	5%-6%	Binder
Benzalkonium Chloride	0.25%-1%	Conditioner, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	0.05%-0.1%	Neutralizing Agent

TABLE 10-continued

Ingredient	Percent Range	Function
Wheat Protein		
Sodium Hydroxide	0.05%-0.1%	Neutralizing Agent

All of the formulations described in TABLE 1-10 representing various embodiments of the Present Invention operate in the manner that was disclosed herein. The same results may be achieved by varying the percentages for the active and inactive ingredients. Varying the percentages for the active ingredients affects the potency of the formulation. Varying the percentages for the inactive ingredients affects the consistency of the formulation. The desired results may be achieved by varying the ingredients and their amounts by those skilled in the art without undue experimentation.

I claim:

1. A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:

a) electrostatically attracting the particulate matter to the thin film;

b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,

c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.

2. A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidic agent, and wherein said formulation, once applied:

a) electrostatically attracts the particulate matter to the thin film;

b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,

c) inactivates the particulate matter and renders said particulate matter harmless.

3. The formulation of claim **2** wherein the at least one cationic agent is a polymeric quaternary ammonium compound.

4. The formulation of claim **3** wherein the at least one polymeric quaternary ammonium compound is taken from the group consisting of:

Polyquaternium-10,
Polyquaternium-22,
Polyquaternium-67,
Polyquaternium-70,
Polyquaternium-72, and
Polyquaternium-88.

5. The formulation of claim **2** wherein the at least one cationic agent is Cocodimonium Hydroxypropyl Hydrolyzed Keratin or Hydroxypropyltrimonium Wheat Protein.

6. The formulation of claim **2** wherein the at least one cationic agent is Benzalkonium Chloride.

7. The formulation of claim **2** wherein the at least one biocidic agent is Benzalkonium Chloride or Lysine HCL.

8. A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising:

a) at least one biocidic agent, and

b) at least one quaternary thickener.

9. The formulation of claim **8** wherein the at least one biocidic agent is Benzalkonium Chloride or Lysine HCL.

10. The formulation of claim **8** wherein the at least one quaternary thickener is taken from the group consisting of:

Polyquaternium-10,
Polyquaternium-22,
Polyquaternium-67,
Polyquaternium-70,
Polyquaternium-72, and
Polyquaternium-88.

11. The formulation of claim **8** wherein the at least one cationic agent is Cocodimonium Hydroxypropyl Hydrolyzed Keratin or Hydroxypropyltrimonium Wheat Protein.

12. The formulation of claim **8** wherein the at least one cationic agent is Benzalkonium Chloride.

13. The formulation of claim **8** further comprising:

a) water,

b) a preservative,

c) a conditioner, and

d) an emulsifier.

14. The formulation of claim **13** further comprising a neutralizing agent added to adjust a pH in the range of 5.0 to 6.8.

15. The formulation of claim **13** further comprising a surfactant.

16. The formulation of claim **13** further comprising a thickener.

17. The formulation of claim **13** further comprising an emollient.

18. The formulation of claim **13** further comprising a humectant.

19. The formulation of claim **13** further comprising a binder.

20. The formulation of claim **13** wherein the preservative is taken from the group consisting of:

Phenoxyethanol,
Methylparaben,
Butylparaben,
Ethylparaben, and
Isobutylparaben.

21. The formulation of claim **13** wherein the emulsifier is taken from the group consisting of:

Cetyl Alcohol,
Cetearyl Alcohol,
Glyceryl Stearate,
Ceteareth-20,
PEG-40 Stearate,
Dicetyl Phosphate,
Ceteth-10 Phosphate.

22. The formulation of claim **16** wherein the thickener is Cetyl Alcohol or Stearyl Alcohol.

23. The formulation of claim **13** wherein:

a) the amount of water ranges from 54% to 90% by weight

b) the amount of the quaternary thickener ranges from 0.5% to 5.0% by weight,

c) the amount of biocidic agent ranges from 0.25% to 2% by weight,

d) the amount of emulsifier ranges from 0.5% to 4% by weight.

* * * * *

EXHIBIT 5

Covixyl-G Product Packaging

COVIXYL-G

Drug Facts

Active Ingredient — Purpose
Benzalkonium chloride (0.13%) — Antiseptic

Uses
- Kills germs
- Help reduce bacteria on the skin

Warnings
For external use only

Do not use
in the eyes. In case of contact, rinse out thoroughly with water.
if you have allergies any of the ingredients listed.
if you have a history of nasal bleeding / irritation.

Stop use and ask a doctor if rash, irritation, or other allergic reaction occurs.

Keep out of reach of children. If the product is swallowed, get medical help or contact a Poison Control Center right away.

Directions
Apply to skin at the rim of nose and inside of nostrils
- For adults and children over 12 years of age
  1. Shake the bottle before use. Apply 2~4 drops of solution to the cotton swab.
  2. Apply liberally to the skin inside and around each nostril by rotating for 10 seconds covering all surfaces. Do not extend the swab into the nose beyond the swab tip. Discard used swab.
  3. Reapply every 4-6 hours or as needed.
- Children under 12 years of age: an adult should supervise use
- Children under 2 years of age: ask a doctor prior to use

Other Information
Store at 20°~25°C (68°~77°F).

Inactive Ingredients
copper gluconate, glycerin, xylitol, phenoxyethanol, 1,2 hexanediol, sodium hydroxide, citric acid, PVP, lavender oil, castor oil, water

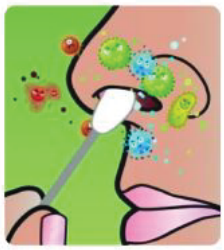
Questions? call 1-201-431-9052
Distributed by Salvacion USA, Inc. Englewood Cliffs, NJ 07632

quickly and effectively

COVIXYL-G

Easy and Safe

Simply Shake, Drop & Swab



swab the skin just inside and around the nose

COVIXYL-G

NASAL ANTISEPTIC SOLUTION

Nanotechnology Delivery System

- Kills 99.99% of Germs
- No Irritation
- Lasts up to 6 Hours
- Alcohol Free
- Lavender Scent

40+ Treatments

COTTON SWAB SOLD SEPARATELY

0.676 fl oz (20ml)

NDC

ACTUAL SIZE

EXHIBIT 6

U.S. Patent Application Publication No. 2022/0133783 A1

US 20220133783A1

(19) **United States**

(12) **Patent Application Publication**

(10) **Pub. No.: US 2022/0133783 A1**

(43) **Pub. Date: May 5, 2022**

GAFFAR et al.

(54) **ANTIVIRAL COMPOSITION AND USE OF THE SAME**

(71) Applicant: **SALVACION USA INC.**, Englewood Cliffs, NJ (US)

(72) Inventors: **Abdul GAFFAR**, Lakewood Ranch, FL (US); **Yeong Wan CHO**, Palisades Park, NJ (US); **Sei Young YUN**, Daejeon (KR)

(73) Assignee: **SALVACION USA INC.**, Englewood Cliffs, NJ (US)

(21) Appl. No.: **17/576,098**

(22) Filed: **Jan. 14, 2022**

Related U.S. Application Data

(63) Continuation-in-part of application No. PCT/US20/55772, filed on Oct. 15, 2020.

(60) Provisional application No. 63/103,881, filed on Aug. 31, 2020.

Publication Classification

(51) **Int. Cl.**

A61K 33/34	(2006.01)
A61K 9/107	(2006.01)
A61P 31/12	(2006.01)
A61K 47/16	(2006.01)

(52) **U.S. Cl.**

CPC ***A61K 33/34*** (2013.01); ***A61K 47/16*** (2013.01); ***A61P 31/12*** (2018.01); ***A61K 9/1075*** (2013.01)

(57) **ABSTRACT**

Provided are an antiviral composition containing a cationic antiviral agent (cationic agent) and a copper salt to prevent, control or treat viral infections in a mammal, particularly in the nasopharyngeal and throat areas of humans and animals, and a method of preventing, controlling or treating viral infections in a mammal using the same.

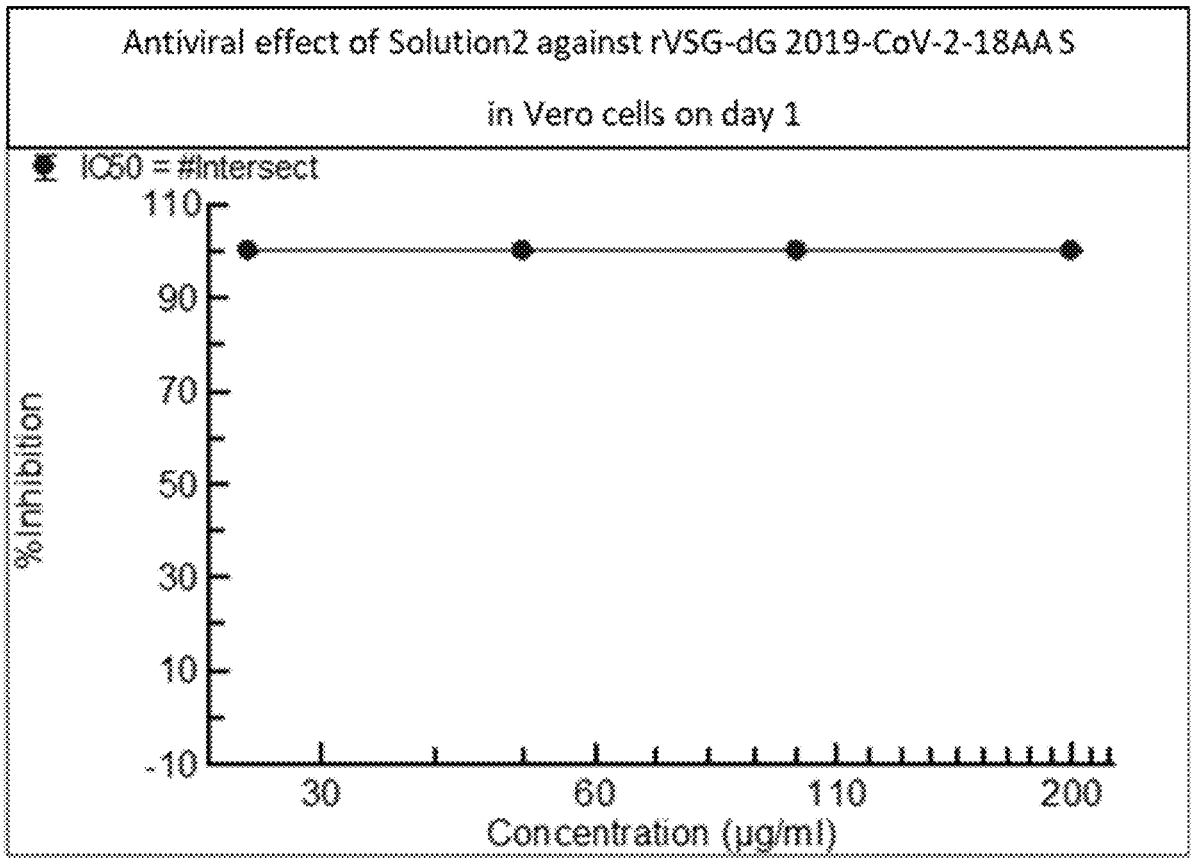


FIG. 1

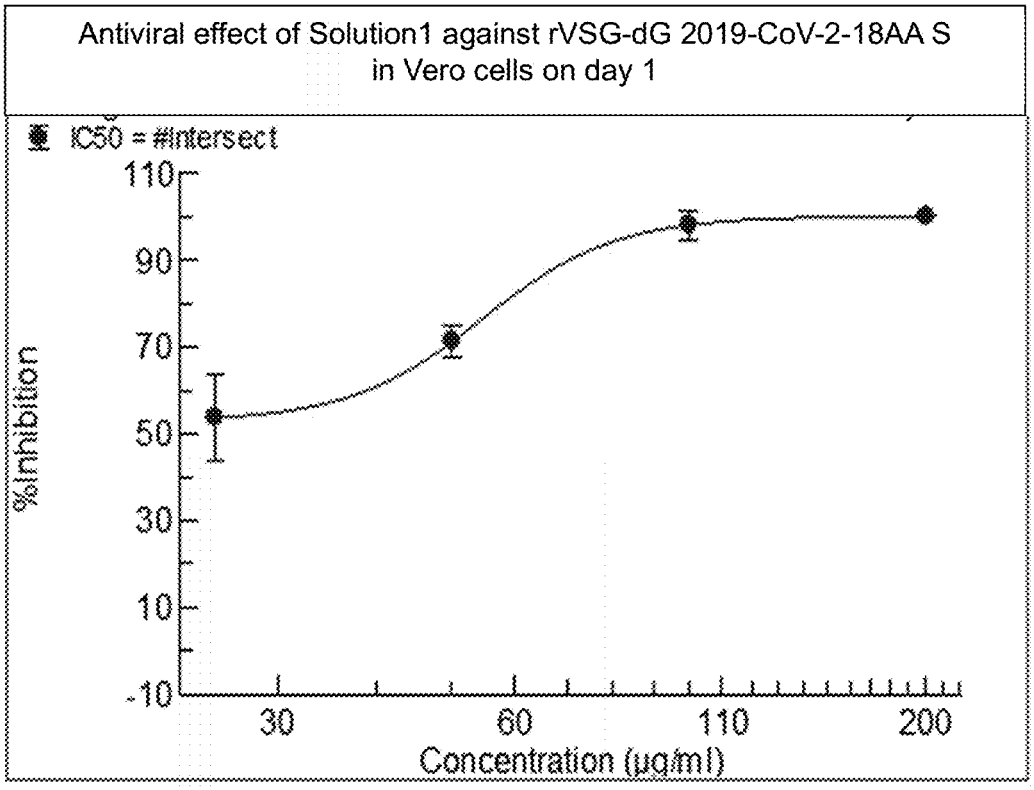

Antiviral effect of Solution1 against rVSG-dG 2019-CoV-2-18AA S in Vero cells on day 1
IC50 = #intersect
110
90
70
50
30
10
-10
%Inhibition
30
60
110
200
Concentration (µg/ml)

FIG. 2

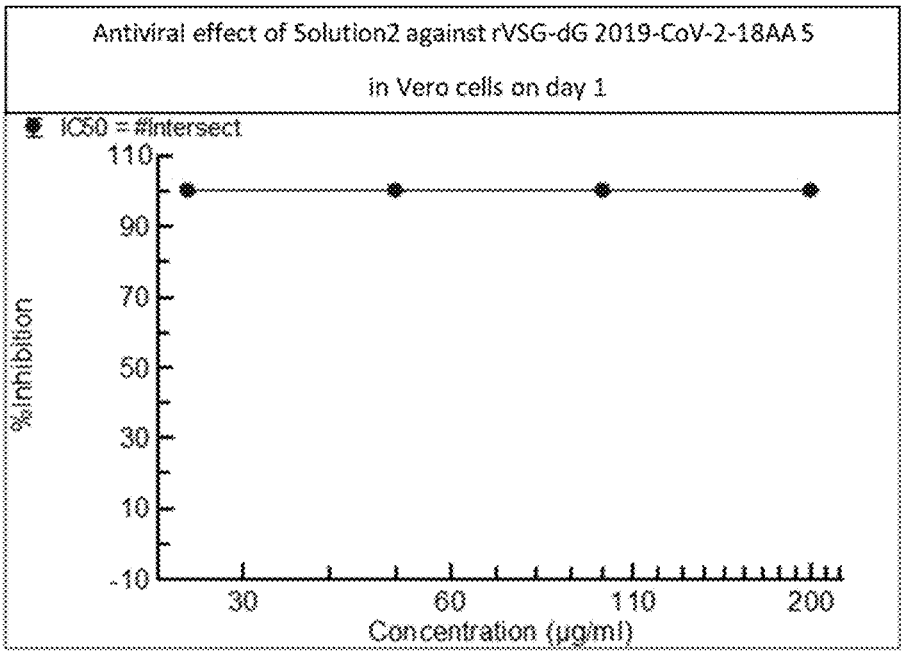

Antiviral effect of Solution2 against rVSG-dG 2019-CoV-2-18AA 5
in Vero cells on day 1
IC50 = #intersect
110
90
70
50
30
10
-10
%Inhibition
30
60
110
200
Concentration (µg/ml)

FIG. 3

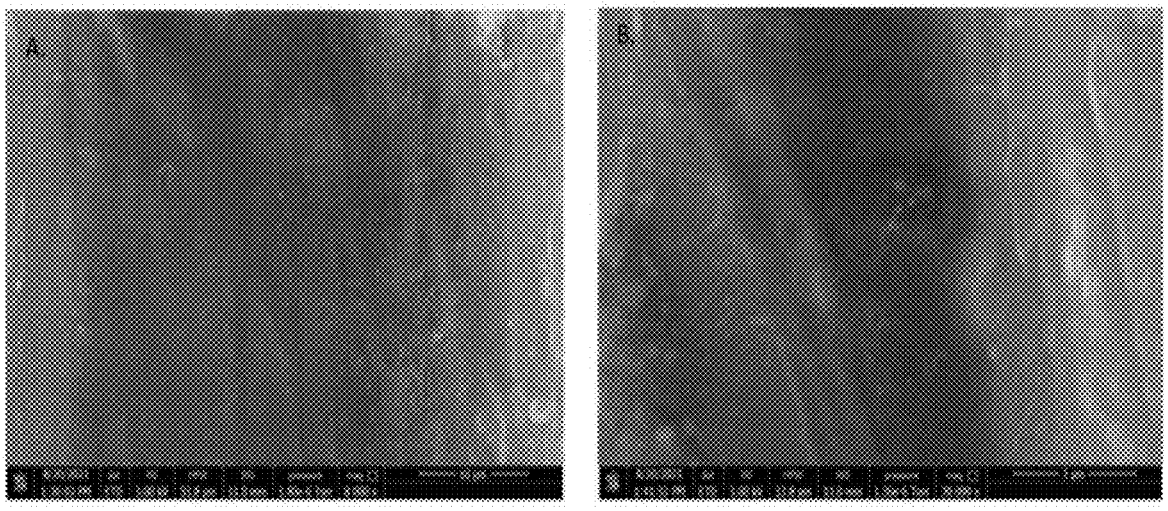


FIG. 4

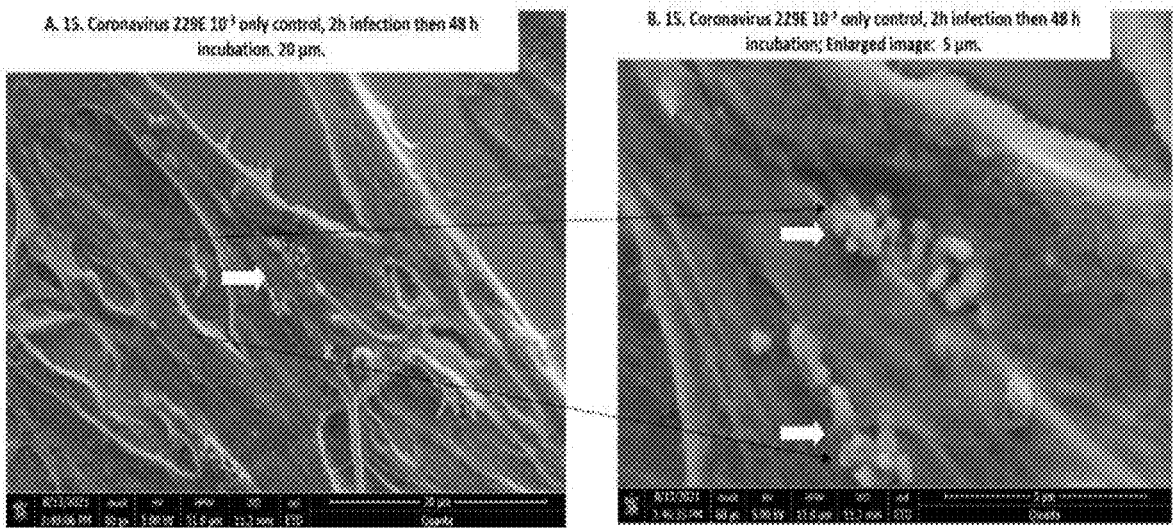
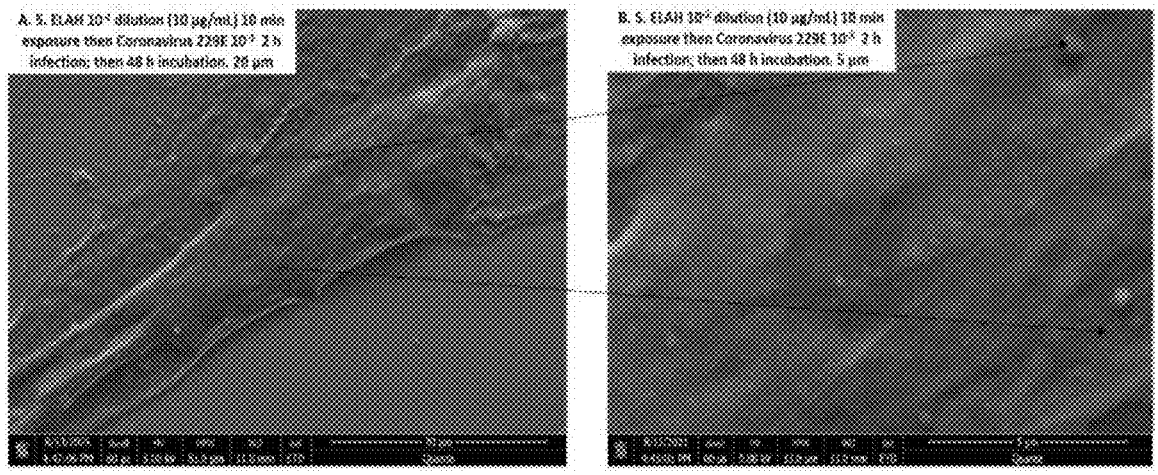

A. 15. Coronavirus 229E 10⁻³ only control, 2h infection then 48 h incubation. 20 µm.
B. 15. Coronavirus 229E 10⁻³ only control, 2h infection then 48 h incubation; Enlarged image: 5 µm.

FIG. 5


A. S. ELAH 10⁻¹ dilution (10 µg/mL) 10 min exposure then Coronavirus 229E 10⁻³ 2 h infection; then 48 h incubation. 20 µm
B. S. ELAH 10⁻¹ dilution (10 µg/mL) 10 min exposure then Coronavirus 229E 10⁻³ 2 h infection; then 48 h incubation. 5 µm

ANTIVIRAL COMPOSITION AND USE OF THE SAME

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a Continuation-in-Part of PCT Application No. PCT/US2020/055772, filed on Oct. 15, 2020, which claims priority to and the benefit of U.S. Provisional Patent Application No. 63/103,881, filed on Aug. 31, 2020, the disclosure of which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] This invention relates to an antiviral composition containing a cationic antiviral agent (cationic surfactant) and a copper salt to control viral infections in the nasopharyngeal and throat areas of humans and animals.

BACKGROUND OF THE INVENTION

[0003] Acute Respiratory Syndrome (SARS) virus and Covid virus were first found in China and rapidly spread over Asia, Europe, North America, etc. Current evidence suggests that the virus spreads between people through direct, indirect (through contaminated objects or surfaces), or close contact with infected people via mouth and nose secretions. These include saliva, respiratory secretions or secretion droplets.

[0004] Worldwide outbreaks of Covid virus infection illustrate the complexity of effective treatments. Recently, worldwide outbreaks of Covid and SAR infections led to an urgent search for optimum tools to limit the spread of diseases.

[0005] Coronavirus family includes alpha coronaviruses 229E, NL63, Beta 0043, HKU1, and human corona viruses are MER 6-COV C Middle East respiratory Syndrome. SAR-COV (beta coronavirus that cause respiratory syndrome SARS and SAR-COV-2 and the novel coronavirus that cause Coronavirus 2019, Covid-19.

[0006] People around the world commonly get infected with human coronavirus 229E, NL63, 0043, and HKU1. It is believed in the art that Covid-19 is a good experimental model for determining the biological activity of a synergistic combination against Covid viruses.

[0007] Cationic surfactants' anti-bacterial functions are well known in the art for a variety of applications as anti-germ agents, such as water/oil emulsion in nanoparticles as disclosed in U.S. Pat. No. 8,877,208.

[0008] A copper salt has been used in fighting infections (see Gadi, Borkov. Current Chemical Biology 2012, 6; Borkov, G et al 2007, Antimicrobial Agents Chemotherapy Vol 51 page 2605.

[0009] Cationic surfactants derived from lauric acid and arginine, in particular, the ester of lauramide of arginine monohydrochloride, also known as ethyl-N-alpha-lauroyl-L-arginate HCl, lauramide arginine ethyl ester, lauric arginate ethyl ester, or ethyl lauroyl arginine hydrochloride (ELAH), may be used for protection against the virus. The ELAH and its derivatives are described in WO 2008/014824 and the disclosure is incorporated herein by reference in its entirety.

[0010] Among the most common cationic antibacterial or antiviral is a quaternary ammonium compound disclosed in U.S. Pat. Nos. 2,984,639; 3,325,402; 3,431,208 and British Patent No. 1,319,396, each of which is incorporated herein by reference in its entirety.

[0011] Safe and effective antiviral products for the treatment of viral infections are urgently needed, particularly considering the current worldwide break of Covid-19. There is an urgent need in the art for safe and effective new treatments for viral infections.

SUMMARY OF THE INVENTION

[0012] The present inventors have found that a composition comprising a cationic antiviral agent, a copper salt and water shows a surprising, remarkably strong synergistic antiviral activity. Particularly, a composition comprising a cationic surfactant, ELAH or benzalkonium chloride (BAC), in combination with a copper salt showed a synergistically improved antiviral activity, which is unexpected from each of the components when they used alone. Further, the present inventors have found that the composition, when it is applied to the nasal cavity, forms a physical barrier on the surface of the cavity, particularly the surface of the nasopharynx, and protects the virus from adhering to mucosal tissue of the nasal passages, thus stopping further transmission for infection. Accordingly, one object of the present invention is to provide an antiviral composition, particularly an antiviral microemulsion composition comprising an effective amount of a cationic antiviral agent, particularly an arginine ester cationic surfactant, a copper salt and a solvent. Another object of the present invention is to provide a method of preventing, inhibiting or treating a viral infection in a subject in need thereof comprising applying the composition to the subject, particularly to the nasal cavity of the subject.

[0013] One aspect of the present invention relates to an antiviral composition comprising a cationic antiviral agent, a copper salt and water.

[0014] The cationic agent in the composition may be in an amount of 2 ppm to 20,000 ppm, and the copper salt may be in an amount of 1 ppm to 10,000 ppm. The solvent in the composition may be selected from one or more of water, alcohol, propylene glycol, ethyl acetate, methyl isobutyl ketone, acetone, tetrahydrofuran, isopropyl ether, and a combination thereof. The cationic agent is selected from the group consisting of ethyllauroyl arginate, a quaternary ammonium compound, benzalkonium chloride, benzethonium chloride, methylbenzethonium chloride, cetalkonium chloride, cetylpyridinium chloride, cetrimonium, guanidine, and a combination thereof. The copper salt comprises a gluconate, a citrate, an acetate, an amino acid or a peptide.

[0015] The antiviral composition may comprise 0.01% to 20% of a plasticizer selected from glycol, glycerin, xylitol, ethanol, and a combination thereof.

[0016] In the antiviral composition, the cationic agent and the copper meets Equation 1 described below. In the equation, FICI means Fractional inhibitory Concentration (FIC) Index, FICA means the FIC of agent A, FICB means the FIC of agent B. Herein, agent A is the cationic agent and agent B is the copper agent.

$$FICI=FIC_A+FIC_B. \quad \text{[Equation 1]:}$$

[0017] In the equation, FICA=[CA]sy/[CA]al and FICB=[CS]sy/[CS]al. [CA]al is a minimum inhibitory concentration (MIC) of the cationic agent, and [CS]al is a minimum inhibitory concentration (MIC) of the copper salt, [CA]sy is

a minimum inhibitory concentration (MIC) of the cationic agent where the cationic and the copper agents are used at the same time, and [CS]sy is a minimum inhibitory concentration (MIC) of the copper salt where the cationic the a copper salt are used at the same time.

[0018] In the antiviral composition, the fractional inhibitory index (FICI) is less than 0.5. FICI<0.5 indicates synergistic, FICI of >1 indicates additive, and FICI of >2 indicates indifferent (Hollander et al: Antimicrobial agents Chemotherapy 1998, Vol. 42, pages 744-748).

[0019] The antiviral composition has a pH between pH 4 and pH 8. The pH may be between 4 and 6.5, between 4 and 5, between 4.4 and 5, or between 4.6 and 5.

[0020] The antiviral composition may be formulated into or be in the form of, for example, a nasal spray, a nasal gel, an aerosol, a throat lozenge, a gargle, an oral strip, a topical formulation, or an external use formulation. However, it is not limited to the formulations.

[0021] Where the antiviral composition is applied to a surface, it may be used in an amount of 0.01 to 100 mg/dm^2, preferably 0.5 to 50 mg/dm^2, and more preferably 1 to 19 mg/dm^2.

[0022] Another aspect of the invention relates to a method for preventing, inhibiting, controlling or treating bacterial or viral infections in a subject in need thereof, comprising administering or applying the composition containing a cationic antiviral and a copper salt, as described above, to a subject in need thereof, particularly to the nasal cavity of the subject, more particularly to the nasopharyngeal or throat surface of humans and animals.

[0023] In one embodiment, the composition is pre-administered to the subject for prophylactic effect, wherein the composition reduces viral entry and the cytopathic effect thereof. The composition, when it is administered nasally, is retained in the nasal cavity for a prolonged time, for example, 2 hours or longer, and reduces viral entry and the cytopathic effect of the virus.

[0024] Both the foregoing summary of the invention and the following brief description of the drawings and the detailed description of the invention are exemplary and explanatory and are intended to provide further details of the invention as claimed. Other objects, advantages, and novel features will be readily apparent to those skilled in the art from the following detailed description of the invention. The present invention will be described in detail as follows.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] FIG. **1** illustrates antiviral effect of Solution1 against rVSG-dG 2019-CoV-2-18AA S in Vero cells on day 1.

[0026] FIG. **2** illustrates antiviral effect of Solution2 against rVSG-dG 2019-CoV-2-18AA S in Vero cells on day 1.

[0027] FIG. **3** illustrates SEP imaging photos of MRC-5 cells alone as control after 48-hour incubation at 35° C. A: 10 μm; B: 3 μm.

[0028] FIG. **4** illustrates SEP imaging photos of MRC-5 cells after 2-hour exposure to human coronavirus 229E (10^{-3} dilution) (A) and after rinsing to remove virus and 48-hour incubation (B). A: 20 μm; B: 5 μm.

[0029] FIG. **5** illustrates SEP imaging photos of MRC5 cells after 10-minute exposure to 10 μg/mL (10^{-2} dilution) of active ELAN (non-cytotoxic concentration) (A), and after 2-hour exposure to coronavirus 229E (10^{-3} dilution) and 48-hour incubation (B). A: 20 μm; B: 5 μm.

DETAILED DESCRIPTION OF THE INVENTION

[0030] The antiviral composition provided herein comprises a cationic agent with antiviral activity, a copper salt and a solvent. The cationic agent may be selected from ethyl lauroyl arginate, quaternary ammonium compounds, and guanidine compounds.

[0031] The cationic antiviral agent may be a cationic surfactant, which is derived from lauric acid and arginine, in particular, the ester of lauramide of arginine monohydrate, hereafter named, ELAN, and may be used for protection against virus. Details of ELAN and its derivatives are described in WO 2008/014824, the content of which is incorporated herein by reference in its entirety.

[0032] The cationic antiviral agent may be quaternary ammonium compounds, which are disclosed in U.S. Pat. Nos. 2,984,639; 3,325,402; 3,431,208 and British Patent No. 1,319,396, each of which being incorporated herein. The quaternary ammonium compounds of the cationic antiviral may include those in which one or two substitutions of the quaternary nitrogen has a carbon chain length of typically alkyl groups 8 to 20, typically 10 to 18 while the remaining substituents have lower carbon atoms typically alkyl or benzyl groups such as 1 to 7 atoms, typically methyl or ethyl groups. These include benzalkonium chloride, cetyl pyridinium chloride.

[0033] The cationic antiviral may be guanidine compounds which are disclosed in German Patent application No. P 2,233,383 and it is incorporated herein.

[0034] The copper salt used is a copper salt releasing copper ions in water. The copper salt comprises a gluconate, a citrate, an acetate, amino acids, peptides and complexes of copper/polymer.

[0035] Non-limiting examples for copper (II) salts include Copper (II) sulfate, Copper (II) chloride, Copper (II) hydroxide, Copper (II) perchlorate, Copper (II) selenite, Copper (II) sulfide), Copper (II) thiocyanate, Copper (II) triflate, Copper (II) tetrafluoroborate, Copper (II) acetate triarsenite (Paris Green), Copper (II) benzoate, C (Scheele's Green), Copper (II) chromite, Copper (II) gluconate, Copper (II) peroxide, Copper (II) usnate.

[0036] A copper salt of the amino acids and peptides are disclosed by P. A. Kober and K. Surguira (J. Bio. chem., vol X111 no 1 pages 1-11), the content of which is incorporated herein, and it may include the salts of glycine, alanine, aminobutyric acids, valine, leucine, isoleucine and di- and polypeptides of amino acids.

[0037] Copper polymeric complexes such as acrylic acids, polymers, oligomers, copolymer of maleic acids and/or anhydrides and of olefin having one or more atoms of carbon atoms per molecule may be used. The preferred are polymeric polymaleate, polymethyl methacrylate, vinylmethy ether copolymer and other carboxylic polymer disclosed in U.S. Pat. No. 4,217,343, the content of which is incorporated herein by reference.

[0038] The most preferred combination of the components is ELAH or Benzalkonium chloride with a copper salt to achieve synergistic antiviral effects.

[0039] The composition further comprises 0.01%-20% of a plasticizer, wherein the plasticizer may be selected from glycol, glycerin, ethanol, and a combination thereof.

[0040] It is preferred to dissolve the compounds directly before use in one of the preferred solvents of food-grade water, ethanol, glycerin, propylene glycol and a mixture of glycol with water. If the treatment shall be performed at specific pH values (pH 4 to pH 8), the use of a corresponding buffer solution may be recommended. On the other hand, the synergistic combination can be easily used as a semisolid or a solid. Surfaces shall be protected, for instance, the surface of masks, solid surfaces on the furniture, protective clothes, etc.

[0041] The present invention relates to the use of the combination of a cationic surfactant, ELAH or BAC, and a copper salt to achieve a synergistic antiviral effect against virus infections.

[0042] The present invention furthermore relates to the application of the cationic surfactants of formula with a copper salt to a subject in need thereof, particularly animals or human beings directly, for prophylactic, inhibiting or therapeutic treatment of virus diseases. A "subject in need" refers to a human or animal at risk of a viral infection, or which has contracted a viral infection.

[0043] The cationic surfactants of the formula disclosed in WO 2008/0014824 plus a copper salt may be applied to a surface as a solution. This is the easy and suitable manner of treating the surface of the ground, cars, animals and people. For other applications, it may be more suitable to apply the cationic surfactants plus a copper salt as a solid which may be equally effective.

[0044] The treatment of product to avoid any kind of virus infection might involve the presence of a concentration of the cationic surfactants of the formula, ELAH or BAC with a copper salt, more in particular according to the embodiment of ELAH or BAC of around 2 to 20,000 ppm plus a copper salt 1 to 10,000 ppm product to be protected, preferably a concentration of 100 to 10,000 ppm and more preferably 200 to 2000 ppm. This is a similar concentration as has been described for achieving the microbiocidal action. Products to be treated with the above-indicated range of concentrations of the cationic surfactants plus a copper salt are for instance food products or cosmetics.

[0045] The treatment of surfaces that are infected with viruses, such as the surface of food preparations, the surface of cosmetics, ground surface, the surface of any kind of vehicles, and the surface of any equipment used in the handling of animals infected with the virus, requires the presence of cationic surfactant ELAH or BAC plus a copper salt, in particular according to a preferred embodiment of ELAH or BAC plus a copper salt of level which is sufficient to achieve the wanted antiviral activity at such surfaces. Such level of concentration would be expected 2 to 20,000 ppm, more preferred 100 to 10,000 ppm and even more preferred 100 to 10000 ppm and even more preferred 200 to 2000 ppm, containing the surfactant plus a copper salt of claims, according to the preferred containing ELAN, BAC and a copper salt. These concentrations are given in terms of the concentration of a solution containing the cationic surfactant plus a copper salt which is applied to the surfaces to be treated. If surfaces are treated with solid preparation of the cationic surfactant of the formula, the amount which is applied shall be such that the amount of the cationic surfactant of ELAN or BAC plus a copper salt shall be in the range of 0.01 to 100 mg/dm^2, preferably an amount of 0.5 to 50 mg/dm^2, and more preferably an amount of 1 to 19 mg/dm^2.

[0046] The treatment of liquid preparations such as drinking fluids or natural sources of water such as lakes or ponds requires the presence of the cationic surfactants, more in particular, according to the preferred embodiment of ELAN or BAC plus a copper salt at a concentration of a level which is sufficient to achieve the wanted antiviral in the drinking fluid or water. Such level of concentration would be expected in the range of 0.2 to 20,000 ppm, more preferred 2 to 15,000 ppm, even more preferred 100 to 10,000 ppm and most preferred 200 to 2,000 ppm containing the cationic surfactants ELAN or BAC with copper salt according to the preferred embodiment containing ELAN or BAC plus copper salt. These concentrations are provided in terms of the concentration of the cationic surfactant in the liquid or the water to be treated.

[0047] The treatment of animals or humans implies the application of the cationic surfactant in a manner which is suitable for the application of the compounds used according to one aspect of the invention. The compounds may be applied topically, such as rectal application, external application to the skin or trans-nasal application. The formulations to be applied may be a conventional formulation, such as capsules, microcapsules, tablets, granules, powder, pills, ointments, suppositories, oral strips, suspensions, syrups, emulsions, liquids, sprays, inhalants, and nose drops. Preferably, it is a spray, solution, or microemulsion.

[0048] In one embodiment, the antiviral composition is microemulsion. A microemulsion is a thermodynamically stable fluid, the particle size of which may range from about 10 nm to 300 nm. Because of the small particle sizes, microemulsions appear as clear or translucent solutions.

[0049] The microemulsion composition according to the present invention may have particle sizes of 10 to 300 nm, preferably 10 to 200 nm, 10 to 180 nm, 10 to 60 nm, 20 to 40 nm, or 25 to 40 nm.

[0050] The microemulsion composition was characterized for size and size distribution using several techniques, dynamic light scattering (DLS), asymmetric-flow field flow fractionation (AF4), and light scattering (DynaPro). In addition, particle concentration by light scattering, zeta potential, ELAH concentration by reversed phase high performance liquid chromatography (RP-HPLC), and total and free copper as well as the presence of metal impurities by inductively coupled plasma mass spectrometry (ICP-MS) were also measured.

[0051] In one embodiment, the hydrodynamic size measured by Dynamic light scattering (DLS) in 10 mM NaCl (zeta potential conditions) and PBS (to mimic physiological ionic strength) showed several size populations and that the majority of particles have about 14 nm particles. The particle size measured with the light scattering (DynaPro®) in another embodiment showed that the majority of particles of the microemulsion composition have an average particle size of 14.8±2.3 nm, with an average particle concentration of 1.46±0.97 E+13 particles/ml.

[0052] The size distribution assessed using asymmetric-flow field flow fractionation (AF4) coupled with MALS and DLS detectors showed two size populations, the first peak having the hydrodynamic size ranging from 20 to 40 nm (25.4 nm on average) and the second peak having the hydrodynamic size ranging from 60-170 nm (93.6 nm on average). Upon incubation with plasma, the first peak had

the hydrodynamic size ranged from 25-40 nm and the second peak had the hydrodynamic size ranged from 35-180 nm (81.1 nm in average).

[0053] The microemulsion composition was evaluated for potential contamination with endotoxin and beta-glucans. Endotoxin was assayed using the kinetic turbidity Limulus Amebocyte Lysate (LAL) assay, and beta-glucans were assayed using the commercial Glucatell assay. Both endotoxin and beta-glucan levels were below the assay detection limits, and therefore, are not expected to pose a safety concern.

[0054] The above-mentioned formulations may be prepared according to conventional methods using various organic or inorganic carriers, excipients or additives conventionally used for topical or external formulations, such as plasticizers, pH adjusters, thickeners, fragrances, emulsifiers, preservatives, stabilizers (such as citric acid, sodium citrate, acetic acid), suspending agents (such as methylcellulose, polyvinylpyrrolidone, aluminum stearate), dispersing agents (such as hydroxypropylmethyl cellulose), diluents (such as water), base waxes (such as cacao butter, white petrolatum, polyethylene glycol) or other suitable ones.

[0055] Non-limiting examples of the plasticizers include glycol, glycerin, xylitol, ethanol, or a combination thereof. The plasticizers may be used in an amount of 0.01% to 20 wt. %, preferably 0.5 to 10 wt. %, and more preferably 5 wt. %.

[0056] Non-limiting examples of the preservatives include phenoxyethanol. The preservatives may be used in an amount of 0.05 to 2.5 wt. %, preferably 0.05 wt. %.

[0057] Non-limiting examples of the humectants include 1,2 hexanediol. The humectants may be used in an amount of 0.1 to 10 wt. %, preferably 5 wt. %.

[0058] Non-limiting examples of the pH adjusters include sodium hydroxide or citric acid. The pH adjusters may be used in an amount to adjust the pH of the composition to be in the range of pH 4.5 to 6.5.

[0059] Non-limiting examples of the thickeners include PVP (K 90). The thickeners may be used in an amount of 1 to 10 wt. %, preferably 1 to 3 wt. %, and more preferably 1 wt. %.

[0060] Non-limiting examples of the fragrances include lavender. The fragrances may be used in an amount of 0.1 to 1 wt. %, preferably 0.01 wt. %.

[0061] Non-limiting examples of the emulsifiers include PEG-40 hydrogenated castor oil. The emulsifiers may be used in an amount of 0.1 to 1 wt. %, preferably 0.01 wt. %.

[0062] The composition of the present invention may be applied 1 to 4 times per day, or as needed.

EXAMPLES

[0063] The following examples are provided to illustrate the present invention. It should be understood, however, that the invention is not to be limited to the specific conditions or details described in these examples. Throughout the specification, any and all references to a publicly available document, including a U.S. patent, are specifically incorporated by reference.

Example 1

[0064] VSV-Pseudo Type Neutralization Assay for SARS-CoV2

[0065] IBT (Integrated Biologic Testing) conducted the study using established a VSV Neutralization assay similar to the system IBT and others have previously reported for filoviruses and SARS-CoV2. Briefly, VSV lacking G has been pseudo typed with SARS-CoV2 Spike protein and produced in HEK293T cells. This system contains luciferase reporter gene which is used for assay readout.

[0066] Specifically, four dilutions of the test combination of ELAH or BAC with copper gluconate, 200, 100, 50 and 25 μg/ml and controls were prepared and mixed with VSV virus in a ratio of 1:1 for 1 hour at room temperature followed by incubation over Vero cells at 37° C. The cells were lysed the following day and luciferase activity was measured to assess antiviral effect of the test compound to block viral entry in the Vero cells. All samples were run in triplicate. Data analysis was conducted using XLFit and Graphed pad Prism.

[0067] Synergistic Effect Between the Cationic Agent (e.g., ELAH or BAC) and Copper Estimated by the Fractional Inhibitory Index (FICI)

[0068] It was found that the antiviral effect (against Covid 19) of the combination is higher, when a copper salt and a cationic antimicrobial agent are used in combination, than the summation of separate use of a copper salt and a cationic antimicrobial agent. The antiviral composition containing the cationic agent and the copper salt in combination, or when the cationic agent and the copper salt are used simultaneously, meets Equation 1:

[0069] [Equation 1] FICI=FICA+FICB, wherein FICA=[CA]sy/[CA]al, FICB=[CS]sy/[CS]al, wherein [CA]al is the minimum inhibitory concentration (MIC) of the cationic agent (ex, ELAH or BAC) alone respectively, CS]al is the minimum inhibitory concentration (MIC) of the copper salt alone respectively, [CA]sy is the minimum inhibitory concentration (MIC) of the cationic agent (ex, ELAH or BAC) when the cationic and the copper agents are used at the same time, [CS]sy is the minimum inhibitory concentration (MIC) of the copper agents when the cationic the copper agents are used at the same time.

[0070] The fractional inhibitory index (FICI) of the composition is less than 0.5, which indicates that the composition has a synergistic antiviral effect. Per established principles of synergism between two active agents, if the fractional inhibitory concentration of two agents, when added, is less than 0.5, synergism is demonstrated. That is, FICI<0.5 is synergistic, FICI of >1 is additive, and FICI of >2 is indifferent (Hollander et al: Antimicrobial agents Chemotherapy 1998, Vol 42 page 744-748).

Example 2

[0071] Spray Solutions and Evaluation of Antiviral Effects Thereof

[0072] To evaluate the antiviral effect of the composition of the present invention, Solution 1 was prepared with the

active ELAH and other components as shown below in the table, according to a method known in the art for preparing a spray solution.

[0073] Solution1:

Ingredient	Function	Dosage
ELAH (20%)	Active	0.1-2 w/v %
Copper Gluconate		0.001-1.0%
Glycerin	plasticizer	1-30 g
Xylitol	plasticizer	1-15 g (5.00 w/v %)
Phenoxyethanol	Preservative	0.01-0.5 g
1,2 hexanediol	Humectant	0.2-5 g
Sodium Hydroxide	pH adjuster	q.s.
Citric acid	pH adjuster	q.s.
PVP (K 90)	Thickener	0.1-5 g
Lavendar	Fragrance	q.s.
PEG-40 Hydrogenated Castor Oil	Emulsifier	0.01-3 g
Purified Water	Solvent	to 100 ml
Total		100 ml
pH		5.0 ± 1.5
Appearance		Transparent Liquid

[0074] Solution2:

Ingredient	Function	Dosage
Benzalkonium Chloride (50%)	Active	0.01-5.0 g (w/v %)
Copper Gluconate		0.001-1.0%
Glycerin	plasticizer	1-30 g
Xylitol	plasticizer	1-15 g (5.00 w/v %)
Phenoxyethanol	Preservative	0.01-0.5 g
1,2 hexanediol	Humectant	0.2-5 g
Sodium Hydroxide	pH adjuster	q.s.
Citric acid	pH adjuster	q.s.
PVP (K 90)	Thickener	0.1-5 g
Lavender	Fragrance	q.s.
PEG-40 Hydrogenated Castor Oil	Emulsifier	0.01-3 g
Purified Water	Solvent	to 100 ml
Total		100 ml
pH		5.0 ± 1.5
Appearance		Transparent Liquid

[0075] Antiviral Activity Test Results:

[0076] The results of viral inhibition of SV Covid-19 by ELAH/copper gluconate combination (Solution 1) are illustrated in FIG. **1**, at the concentration of 25, 50, 100 and 200 μg/ml. The reported effect of ELAH by itself on virus inhibition is 300 μg/ml (WO 2008/014824) and copper by itself is 300 μg/ml (Sagripanti, J C et al Applied environ. microbiol: 1993: vo159:4374-4376). Therefore, FICI for ELAH/copper combinations: ELAH 30/Cu30/300=0.10+0.10=0.20 (inhibition conc. is at 30 ppm) is less than 0.5, which indicates synergism between ELAH and copper against SAR-Covid.

[0077] The results of viral inhibition of SV Covid-19 by BAC plus a copper salt (Solution 2) are illustrated in FIG. **2**. The figure shows BAC plus copper gluconate had 100 percent inhibition on SV CoVid2 at 20 μg/ml. However, BAC by itself has been reported to have antiviral effect at 100 μg/ml (Eric G Romanoswki et al. J. occul. Phamacol therapy. 2019: vo135: pages 311-314). Therefore, FICI for BAC/copper combination: BAC 20/100+Copper 20/300=0.2+0.07=0.27 is lower than 0.5, which indicates synergism between BAC and the copper salt against SAR-CoVid 2.

Example 3

[0078] Characterization of the Nasal Spray Inhibition of Coronavirus 229E Binding to MRC-5 Cells (Solution 1 in Example 2: COVIXYL-V™).

[0079] The efficacy of active ELAH on altering cell susceptibility to viral entry was assessed using SEM, under the condition:

[0080] i. Viral strain and amplification number: Human coronavirus 229E (ATCCO VR-740™)-amplification number: 1

[0081] ii. Cell line: MRC-5 (ATCC® CCL-171™)—passage number: 9

[0082] iii. Viral cell culture medium: Eagle's Minimum Essential Medium (EMEM) 2%, Fetal Bovine Serum, 1% penicillin/streptomycin.

[0083] iv. Product test concentrations: Based on findings from Phase 2a, COVIXYL-V™ 0.1% (1000 μg/mL) was diluted in viral cell culture media to Dilutions of 10^{-2} (10 μg/mL) and 10^{-3} (1 μg/mL active concentration).

[0084] v. Diluent used for test item: Viral cell culture media

[0085] vi. Contact time(s): 10 min for test product

[0086] vii. Incubation conditions: 37° C.±2° C. and 5% CO_2 (MRC-5 cell culture), 35° C.±2° C. and 5% CO_2 (Viral barrier studies)

[0087] viii. Methods of assessment: High Resolution Scanning Electron Microscopy, University of Wyoming.

[0088] Viral Barrier Studies:

[0089] MRC-5 (ATCC® CCL-171™) cells (passage number: 9) were seeded approximately 1×10^5 cells/mL to CELLTREAT® 4 chamber cell culture slides (229164) and incubated 37° C.±2° C. and 5% CO_2 for 4 days until 80% to 90% confluence. At time zero of experimentation, active ELAH dilutions 10^{-2} and 10^{-3} 750 μL (total volume) were applied to cells in the chambers and incubated 37° C.±2° C. and 5% CO_2 for 10 minutes, then culture media containing unbound test product was removed and prepared human coronavirus 229E dilutions (10^{-2}, 10^{-3} and 10^{-4}) in viral cell culture media were applied to wells followed by a 2-hour incubation at 35° C.±2° C. and 5% CO_2. Following incubation, viral cell media was aspirated to remove unbound virus, cells rinsed and incubated 35° C.±2° C. and 5% CO_2 for 48 hours with viral culture media. After 48-hour incubation, chamber cell culture slides were imaged via bright field microscopy (results not provided herein) and processed for SEM fixation.

[0090] SEM Imaging:

[0091] After samples underwent fixation, they were placed in a Kinney Vacuum KSE-2A-M Evaporator under 10^4 Torr vacuum for 24 hours, then sputtered with a 5 nm thick gold coat using a Model 30000 Ladd Research Industries apparatus. Secondary electron and backscattered electron images were collected on a Quanta 250 Scanning Electron Microscope under 10^{-5} Torr vacuum using an accelerating voltage of 5 kV and spot sizes of 2 and 3. Electronic alignments on the electron gun (Gun Alignment, Final Lens Aperture Alignment, and Stigmator Alignment) were performed prior to imaging to optimize resolution.

[0092] Results:

[0093] As shown by FIGS. **3** to **5**, the SEM microscopy studies indicated that pre-treatment with active ELAN 10 μg/mL inhibited human coronavirus 229E binding and replication in the MRC-5 cell line. These data indicate that 10 minutes of pre-treatment of MRC-5 cells with active ELAN 10 μg/mL prior to human coronavirus 229E, reduces viral entry and the cytopathic effects caused by the virus after 48 hours of incubation compared to controls. The composition according to the present invention made the active ELAN to retain in nasal passage for 2 hours and longer. Accordingly, the composition of the present invention is effective for prophylactic effect, preventing the infection by the virus.

[0094] It was found that the nasal spray creates a physical barrier on the nasal surface, preventing the virus from adhering to the mucosal tissue of the nasal passages, thus stopping further transmission. The composition of the present invention is particularly effective in preventing the virus infection because it targets the nasopharynx which has been identified as the main entry point for the virus, and forms a physical barrier like film on the surface of the nasopharynx.

Example 4

[0095] This example is to provide formulations prepared with the composition according to the present invention. With the components described in the following tables, various formulations were prepared for administration of the composition according to the present invention.

[0096] Nasal Sprays

Ingredients	Percent by weight
ELAH (20%)	0.1-2%(w/v %)
Copper gluconate	0.001-1.0%
Micro crystalline cellulose	0.5
Polysorbate80	0.05
Phenoxy ethanol	0.1%
NaOH	to adjust pH 6.5
Purified water	to 100

[0097] Nasal Gels

Ingredients	Percent by weight
ELAH (20%) or BAC	0.01-5%
Copper gluconate	0.001-1.0%
Hydroxyethylcellulose	0.5
Xylitol	5%
NaOH	to adjust pH 6.5
Purified water	to 100

[0098] Lozenges

Ingredients	Percent by weight
ELAH (20%) or BAC	0.01-5%
Copper gluconate	0.001-1.0%
Xylitol	5%
Flavor	1
Binder	To 100

[0099] Mouth Gargle

Ingredients	Percent by weight
ELAH (20%) or BAC	0.01-5%
Copper gluconate	0.001-1.0%
Glycerol	10
Pluronic F108	0.2
Flavor	1
NaOH	to adjust pH 6.5
xylitol	5%
Purified water	to 100

[0100] Surface Treatments

Ingredients	Percent by weight
ELAH	0.01-5%
Copper gluconate	0.01-5%
Fragrance	0.05
HCO 40	0.1
phenoxyethanol at	0.1%
Ethanol	10
NaOH	to adjust pH 6.5
Purified water	to 100

[0101] It will be apparent to those skilled in the art that various modifications and variations can be made in the methods and compositions of the present invention without departing from the spirit or scope of the invention. Thus, it is intended that the present invention covers the modifications and variations of this invention, provided they come within the scope of the appended claims and their equivalents.

What is claimed:

1. An antiviral microemulsion composition comprising an effective amount of an arginine ester cationic surfactant, a copper salt and a solvent.

2. The antiviral microemulsion composition of claim **1**, wherein the cationic surfactant is in an amount of 2 ppm to 20,000 ppm, and the copper salt is in an amount of 1 ppm to 10,000 ppm.

3. The antiviral microemulsion composition of claim **1**, wherein the solvent is selected from the group consisting of water, alcohol, propylene glycol, ethyl acetate, methyl isobutyl ketone, acetone, tetrahydrofuran, isopropyl ether, and a combination thereof.

4. The antiviral microemulsion composition of claim **1**, further comprising 0.01% to 20% of a plasticizer selected from the group consisting of glycol, glycerin, xylitol, ethanol, and a combination thereof.

5. The antiviral microemulsion composition of claim **1**, wherein the arginine ester cationic surfactant is ethyl lauroyl arginine hydrochloride (ELAN).

6. The antiviral microemulsion composition of claim **1**, wherein the copper salt comprises a gluconate, a citrate, an acetate, an amino acid or a peptide.

7. The antiviral microemulsion composition of claim **1**, wherein the cationic surfactant and the copper salt meet Equation 1 and the composition has a fractional inhibitory index (FICI) of less than 0.5:

$$FICI=FIC_A+FIC_B, \quad \text{[Equation 1]}$$

wherein FICA=[CA]sy/[CA]al and FICB=[CS]sy/[CS]al,

wherein [CA]al is a minimum inhibitory concentration (MIC) of the cationic agent, [CS]al is a minimum inhibitory concentration (MIC) of the copper salt,

[CA]sy is a minimum inhibitory concentration (MIC) of the cationic agent where the cationic and the copper agents are used at the same time, [CS]sy is a minimum inhibitory concentration (MIC) of the copper salt where the cationic the a copper salt are used at the same time.

8. The antiviral microemulsion composition of claim **1**, wherein the composition has a pH between pH 4 and pH 8.

9. The antiviral microemulsion composition of claim **1**, wherein the composition is a topical formulation comprising a nasal spray, a nasal gel, an aerosol, a throat lozenge, a gargle, or an oral strip,

10. The antiviral microemulsion composition of claim **1**, wherein the composition is applied to a surface in an amount of 0.01 to 100 mg/dm^2.

11. The antiviral microemulsion composition of claim **1**, wherein the microemulsion has an average diameter of 10 to 200 nm.

12. A method of preventing or treating viral infection in a subject in need thereof, comprising applying the microemulsion composition of claim **1** to the subject.

13. The method of claim **12**, wherein the composition is applied to nasal cavity comprising nostrils, nasopharynx or throat of humans and animals.

14. The method of claim **12**, wherein the composition is a topical formulation comprising a nasal spray, a nasal gel, an aerosol, a throat lozenge, a gargle, an oral strip.

15. The method of claim **12**, wherein the composition is applied in an amount of 0.01 to 100 mg/dm^2.

16. The method of claim **12**, wherein the composition is pre-treated to the subject for prophylactic effect, reducing viral entry and cytopathic effect thereof.

17. The method of claim **12**, wherein the composition allows a prolonged retention of the arginine ester cationic surfactant in nasal cavity.

18. The method of claim **17**, wherein the arginine ester cationic surfactant is retained in nasal cavity for at least 2 hours.

19. The method of claim **17**, wherein the composition forms a physical barrier on the surface of nasal cavity.

20. The method of claim **19**, wherein the composition forms the physical barrier on the surface of nasopharynx.

* * * * *

EXHIBIT 7

Covixyl-V Product & Packaging


Covixyl™
Nasal Spray
Helps Block Airborne Viruses
400 Sprays
0.676 fl. oz. (20ml)


DRUG-FREE
Covixyl
Nasal Spray
Helps Block Airborne Viruses
400 Sprays (20ml)


Covixyl™
Proven Safe and Effective
For COVID-19 and the Flu, follow official guidelines.
Covixyl is designed to work alongside these measures, including vaccines.
These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease.
Formulation protected by US Patent #17/576,098
Made in the USA for Salvacion Int'l, LLC Sheridan, WY 82801
8 60008 89180 8


Product Facts
Uses
Creates a protective barrier in the nasopharynx to help block airborne viruses.
Cautions
• Pregnant women should consult with a healthcare provider prior to use.
• Adult should supervise children under 12.
• Do not share with others.
Directions
1. Shake bottle
2. Insert tip into nostril, angling the bottle backward, not vertical
3. Spray twice in each nostril
4. Use every 6 hours or as needed
Ingredients
Purified Water, Glycerin, Xylitol, 1-2 Hexanediol, Povidone, PEG-40, Ethyl Lauroyl Arginate HCl (0.1%), Phenoxyethanol, Lavender, Copper Gluconate, Sodium Citrate, Citric Acid, Sodium Hydroxide (buffer)
Recycle Me

EXHIBIT 8

Test Report From
Korean Test & Research Institute

BEYOND ASIAN HUB, TOWARD GLOBAL WORLD

KTR KOREA TESTING & RESEARCH INSTITUTE

TEST REPORT

98, Gyoyukwon-ro, Gwacheon-si, Gyeonggi-do, 13810, Korea TEL 82-2-3667-9134 FAX 82-2-3667

Report No : TBK-2021-001478
Receipt Date : 2021.03.09.
Representative : YEONG W CHO
Test Completion Date : 2021.04.
Company name : SALVACION USA INC.
Address : 210 SYLVAN AVENUE #24 ENGLEWOOD CLIFFS, NEW JERSEY 07632-0763

Sample name : COVIXLY-V (active: ELAH 0.1%)

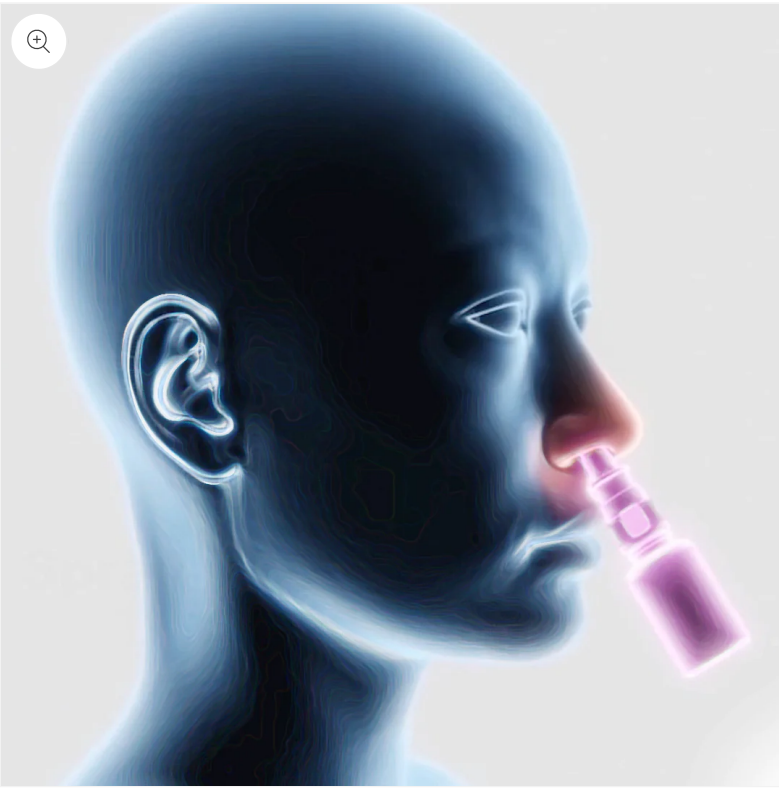
Test Results

TEST ITEM	UNIT	SAMPLE	RESULT	TEST METHOD
Virucidal test [Human respiratory syncytial virus]	Log reduction	-	2.75	ASTM E1052-20
Virucidal test [Rotavirus A]	Log reduction	-	2.13	ASTM E1052-20
Virucidal test [Influenza A virus (H1N1)]	Log reduction	-	1.50	ASTM E1052-20

EXHIBIT 9

Webpage From

www.biosure.co.uk



BioSURE PRO Protective Nasal Spray - block airborne viruses

Protects in seconds, lasts for hours. Your ideal travel companion.

£14.95 GBP

Tax included.

Pack size

Single spray

Twin Pack

Family pack x 4

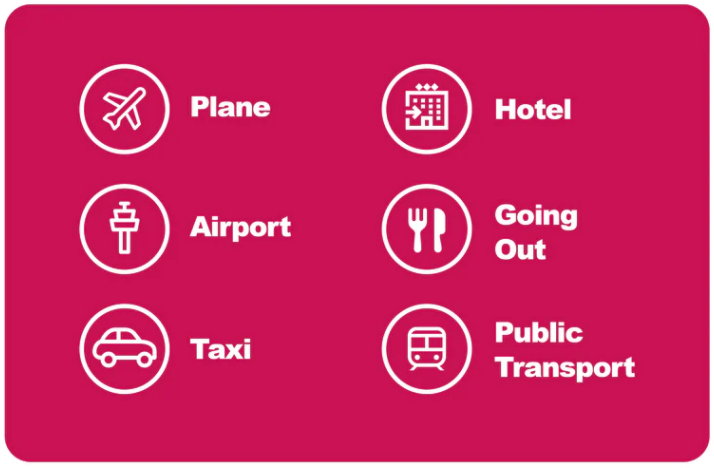
Quantity – 1 +

Buy Now on amazon Add to Bag

Works immediately

Nasal Spray

Proven safe & effective



UKCA marked, MHRA registered

Do you want to enjoy more and worry less this travel season?

BioSURE PRO can help!

Our unique microemulsion formula, is applied as a **plume spray** for optimum coverage and **works in seconds**, providing up to **6 hours of protection** per application.

It creates an **invisible physical barrier** that stops viruses connecting with the cells in your nose. **If viruses can't connect, they can't infect.**

Clinically proven safe and effective, BioSURE PRO is **drug-free** and can be used **daily** and **reapplied as necessary** for continuous protection against common airborne viruses.

Cost Effective - Each bottle contains 400 sprays, which gives 600 hours of protection - that's 3 months supply if used daily!

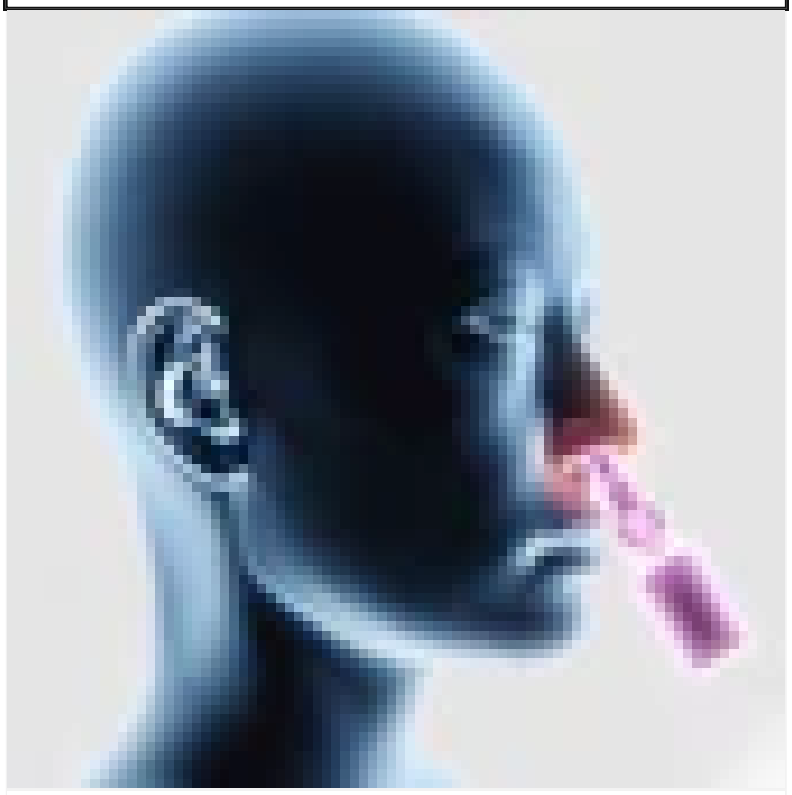

Go

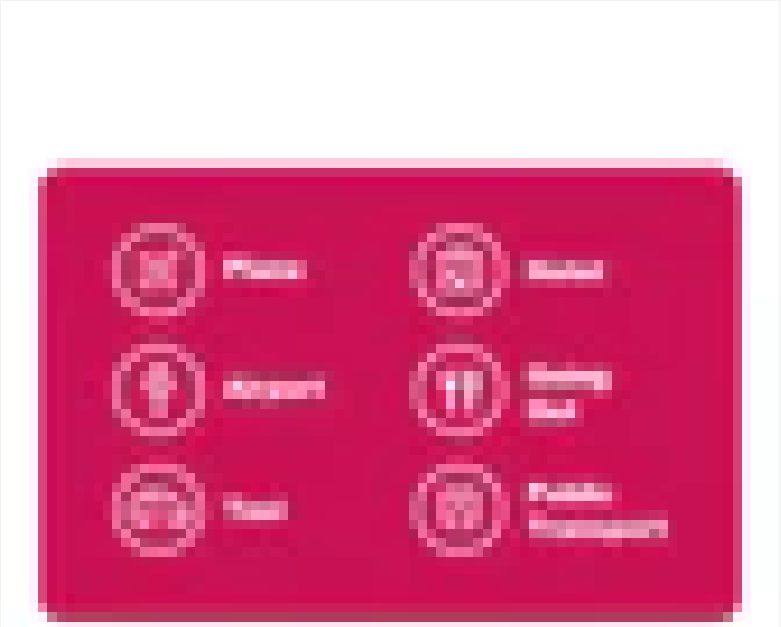

Don't
Miss
Out
bebiosure.com

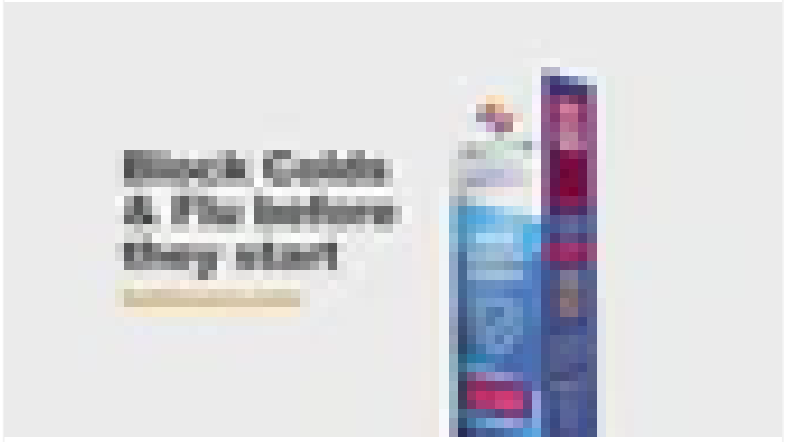

Block Colds
& Flu before
they start
bebiosure.com
BioSURE Pro
Protective
Nasal Spray
Block
Airborne
Viruses
SPRAY
PROTECT
GO
PLAY
WORK
TRAVEL
6 hours of
protection

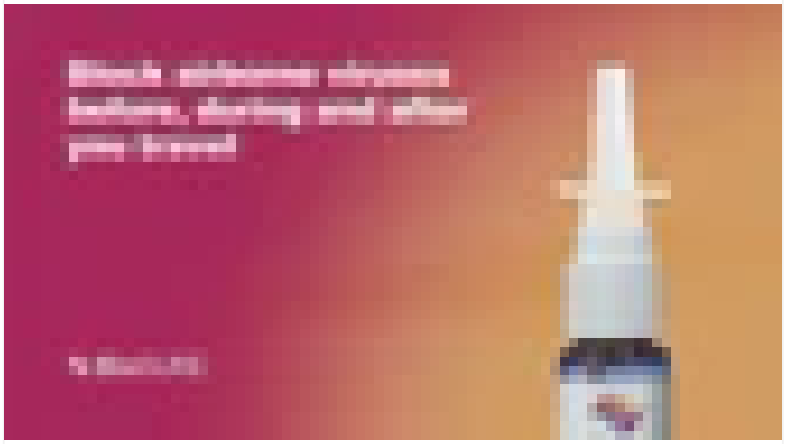

Block airborne viruses
before, during and after
you travel

1/9









How does BioSURE® Pro Protective Nasal Spray work?

BioSure PRO Protective Nasal Spray is a microemulsion formula, that is applied as a plume of droplets rather than a squirt, so it creates a temporary physical barrier in your nasal passages that blocks the virus spike proteins from entering the cells ACE-2 receptors in your nose. This helps block the first step of infection at the main entry point and it also helps prevent the virus from multiplying that physically blocks airborne viruses from attaching to the cells in your nose.

The key ingredient is ELAH (Ethyl Lauroyl Arginine Hydrochloride), that has been safely and effectively used in a globally recognised

Does the BioSURE® Pro Protective Nasal Spray protect against all variants of respiratory viruses?

Studies demontrate that **BioSURE® PRO Protective Nasal Spray** is effective against a number of viruses including RSV, common colds, influenzas (flus) and SARS-CoV-2 (COVID-19) delta and omicron variants. It also blocks Noravirus A which is a common viruses which causes sickness and diarrhoea in addition to flu-like symptoms.

Because the mode of operation is performed by the microemulsion formula being applied as a plume spray rather than a spray and forming an invisible physical barrier in the nose and nasopharynx, in principle it should provide protection against f mutations. We are performi al

mouthwash to block the growth of bacteria in the mouth.

Clinical evaluations in humans and in the lab have proven the effectiveness of ELAH at blocking airborne viruses, including RSV (common cold), influenza (flu) and COVID-19 delta and omicron variants.

Why should I use BioSURE® Pro Protective Nasal Spray?

BioSURE® Pro Protective Nasal Spray is a unique microemulsion that has been proven to help prevent infections caused by some common colds, flu, COVID-19 and other viruses by forming an invisible temporary physical barrier that blocks airborne viruses, including colds, flu and COVID-19, from being able to enter the cells in your nose.

Basically if the virus can't enter these cells, it cannot cause infection and it cannot reproduce.

BioSURE® Pro Protective Nasal Spray is not a medicine and has no pharmacological action, so is safe to use daily. It is a powerful way to help protect yourself against airborne respiratory viruses.

How long does it work for?

The BioSURE® Pro Protective Nasal Spray has been proven to be effective at blocking airborne viruses for **6 hours** after application and it can be reapplied every six hours for continuous protection.

evaluations and studies and will continue these are as new variants of viruses evolve.

How much does it cost to protect myself with BioSURE® PRO?

There are 400 sprays in each BioSURE PRO Protective Nasal Spray, which gives you 100 uses of 6 hours each. That's 600 hours of protection per bottle! So that is under 15p per application and under 2.5p per hour of protection.

Who can use BioSURE® PRO Protective Nasal Spray?

It's suitable for ages 12 years and older.

If you are pregnant it is recommended you consult with a healthcare professional before use.

All of the ingredicents in the BioSURE PRO Protective Nasal Spray are food safe, however this guidance is given as there has not been specific evaluations with pregnant women or children under the age of 12 years.

Is BioSURE® PRO Protective Nasal Spray Safe to Use?

The key ingredient of **BioSURE® Pro Protective Nasal Spray**, is ELAH (ethyl lauroyl arginine HCL), which has been used in mouthwashes and as a food preservative for decades and enjoys a high safety profile. Extensive studies have shown that this ingredient metabolizes qui compounds commonly found

BioSURE PRO has not pharmacoligical or metabolic action, so can be used daily without risk of overdose or addiction and studies show there is no decline in it's effectiveness with long-term use

How long does it take to work? −

As soon as the product has been sprayed into the nostrils, it is effective.

Can I use it every day? −

BioSURE PRO is not a medicine and has no pharmacological or metabolic action. It is proven safe to use daily, without risk of overdose or developing dependencies. There is also no decline in its effectiveness with regular use.

How do I use the spray? −

BioSURE PRO is a unique microemulsion, that is applied as a plume to make an even, effective barrier against airborne viruses.

You do not need to tilt your head back and you do not need to sniff when you apply. Simply remove the lid (and the clip if you use it) and tilt the bottle at an angle. Spray twice into each nostril and the you have that layer of protection for the next 6 hours. Reapply as required.

In our studies, BioSURE PRO has shown no side effects, dependencies from daily use or decrease in it's efficacy from prolonged use.

Can I use BioSURE PRO with other nose sprays, like hayfever prevention and decongestants? −

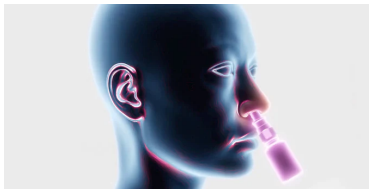
BioSURE PRO is not a medicine and has shown no signs of cross-reaction with a broad range of medications and products.

If you are already using a prescribed or OTC nasal spray for allergies or similar, it is recommended that you apply this spray first and wait a couple of minutes before applying BioSURE PRO, as BioSURE PRO creates a physical barrier that could affect the effectiveness of your medicinal nasal spray.

Nasal Spray Blogs





Why is prevention better than cure?

DECEMBER 23, 2022

We all have our part to play in our own preventative health care and building an all-round healthier community. Developing healthy habits can make us feel better, look better and...

Does exposure to colds and flu strengthen immun...

NOVEMBER 28, 2022

As the winter season approaches, so too do the dreaded cold and flu symptoms. Many of us will experience a cough or runny nose at some point during the winter...

Protect yourself from Colds and Flu this winter

OCTOBER 11, 2022

How can I protect myself from colds and flu this winter? This is a common question asked on Google every day; every winter we are affected by common colds and...

BioSure launch the new protective nasal spray w...

OCTOBER 11, 2022

BioSure launch the new protective nasal spray which protects from colds, flu and coronaviruses Just Spray, Protect and Go BioSure Global are proud to announce the launch of the revolutionary,...

1/3

View all

T: 0845 222 0012
T: +44 (0)1992 815825
E: info@biosure.co.uk
WhatsApp: +44 (0)7763 489170

My Account

Contact Us

Delivery

BioSure Global Ltd,
121 Brooker Road,
Waltham Abbey,

EN9 1JH. UK
United Kingdom
Registered Company Number:
11230071

Privacy Policy

Shipping Policy

Trust Pilot

Terms of Service

Business Enquiries

Press Releases

Subscribe to our emails

Email

Chat with us

EXHIBIT 10

Declaration of Nitin Kumar

DECLARATION OF NITIN KUMAR

I, Nitin Kumar, being of full age, do hereby depose and say:

1. I am a resident of the State of New Jersey.

2. On March 7, 2023, I placed an order online with *amazon.com* for two bottles of Covixyl Nasal Spray. I paid for the merchandise online with my Master Card credit card.

3. I received the ordered merchandise at my home address in New Jersey on March 8, 2023.

4. Upon receipt, I tendered the unopened packages to Trutek Corp.

The above statements are true to the best of my knowledge, and I make said statements under pains and penalties of perjury under the laws of the United States and the State of New Jersey.

Date: 5/31/23

Nitin Kumar

EXHIBIT 11

Declaration of Keith Altman

DECLARATION OF KEITH ALTMAN

I, Keith Altman, being of full age, do hereby depose and say:

1. I am a resident of the State of Michigan.

2. On March 10, 2023, I placed two separate orders online with for Covixyl Nasal Spray. I paid for each merchandise order online with my Visa Card credit card.

3. I received one of the ordered merchandises at my home address in Michigan within approximately 3-4 days after purchase.

4. I shipped one ordered merchandise directly to Trutek Corp. at their corporate New Jersey location. Same was confirmed as received.

The above statements are true to the best of my knowledge, and I make said statements under pains and penalties of perjury under the laws of the United States and the State of Michigan.

Date: July 11, 2023

By: 

Keith Altman